

EXHIBIT 10

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON &)
JOHNSON TALCUM POWDER)
PRODUCTS MARKETING)
SALES PRACTICES AND) MDL 16-2738
PRODUCT LIABILITY) (FLW)(LHG)
LITIGATION)
_____)
THIS DOCUMENT)
PERTAINS TO ALL CASES)

WEDNESDAY, DECEMBER 19, 2018

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Videotaped deposition of Laura Plunkett, Ph.D., DABT, held at the Four Seasons Hotel, 999 North 2nd Street, St. Louis, Missouri, commencing at 9:12 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

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| <p>1 DYKEMA</p> <p>2 BY: JANE E. BOCKUS</p> <p>3 jbockus@dykema.com</p> <p>4 RYAN J. SULLIVAN</p> <p>5 rsullivan@dykema.com</p> <p>6 112 East Pecan Street, Suite 1800</p> <p>7 San Antonio, Texas 78205</p> <p>8 (210) 554-5500</p> <p>9 Counsel for the Defendant Imerys</p> <p>10 Talc America</p> <p>11</p> <p>12 SEYFARTH SHAW LLP</p> <p>13 BY: THOMAS T. LOCKE</p> <p>14 tlocke@seyfarth.com</p> <p>15 975 F Street, N.W.</p> <p>16 Washington, DC 20004</p> <p>17 (202) 463-2400</p> <p>18 Counsel for Defendant Personal Care</p> <p>19 Products Council</p> <p>20</p> <p>21 TUCKER ELLIS LLP</p> <p>22 BY: CAROLINE M. TINSLEY</p> <p>23 caroline.tinsley@tuckerellis.com</p> <p>24 100 South Fourth Street, Suite 600</p> <p>25 St. Louis, Missouri 63102</p> <p>(314) 571-4965</p> <p>Counsel for PTI Union, LLC and PTI</p> <p>Royston, LLC</p> <p>ALSO PRESENT:</p> <p>KATIE TUCKER, Beasley Allen</p> <p>VIDE O G R A P H E R :</p> <p>JACOB ARNDT,</p> <p>Golkow Litigation Services</p> <p>---</p> | <p>1 8 "Weight of Evidence: General 211</p> <p>Principles and Current Applications</p> <p>2 at Health Canada"</p> <p>3 (Exhibits attached to the deposition.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |

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| <p>1 VIDEOGRAPHER: We are now on 2 the record. 3 My name is Jacob Arndt. I'm a 4 videographer for Golkow Litigation 5 Services. 6 Today's date is December 19, 7 2018, and the time is 9:12 a.m. 8 This deposition is being held 9 in St. Louis, Missouri, In Re: Johnson 10 & Johnson Products Marketing Sales 11 Practices, for the United States 12 District Court for the District of 13 New Jersey. 14 The deponent is Dr. Laura 15 Plunkett. 16 Will counsel please identify 17 themselves? 18 MR. MEADOWS: Ted Meadows for 19 plaintiffs. 20 MS. PARFITT: Michelle Parfitt 21 for the plaintiffs. 22 MR. BEATTIE: Ryan Beattie for 23 plaintiffs. 24 MR. TISI: Chris Tisi for 25 plaintiffs.</p> | <p>1 DIRECT EXAMINATION 2 QUESTIONS BY MS. BRANSCOME: 3 Q. All right. Good morning, 4 Dr. Plunkett. I introduced myself right 5 before we started, but my name is Kimberly 6 Branscome, and I am here on behalf of Johnson 7 & Johnson. 8 Is it your understanding today 9 that you are giving your deposition for the 10 purpose of a Daubert analysis in the MDL 11 related to Johnson's baby powder? 12 A. That's my understanding, yes. 13 (Plunkett Exhibit 1 marked for 14 identification.) 15 QUESTIONS BY MS. BRANSCOME: 16 Q. I want to start by handing you 17 what I will mark as Plunkett Deposition 18 Exhibit 1. 19 Do you recognize the document 20 that I just handed you? 21 A. Yes. 22 Q. Okay. Have you seen this 23 document before? 24 A. Yes. 25 Q. All right. When was this</p> |
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| <p>1 MR. GOLOMB: Richard Golomb for 2 plaintiffs. 3 MR. LOCKE: Tom Locke for the 4 Personal Care Products Council. 5 MS. TINSLEY: Caroline Tinsley 6 for PTI Union, LLC, and PTI Royston, 7 LLC. 8 MR. SULLIVAN: Ryan Sullivan 9 for Imerys. 10 MS. BOCKUS: Jane Bockus for 11 Imerys. 12 MR. SMITH: William Smith for 13 Johnson & Johnson. 14 MS. BRANSCOME: Kimberly 15 Branscome for Johnson & Johnson. 16 VIDEOGRAPHER: Thank you. 17 The court reporter is Carrie 18 Campbell and will now swear in the 19 witness. 20 LAURA PLUNKETT, Ph.D., DABT, 21 of lawful age, having been first duly sworn 22 to tell the truth, the whole truth and 23 nothing but the truth, deposes and says on 24 behalf of the Defendant Johnson & Johnson, as 25 follows:</p> | <p>1 document provided to you? 2 A. Either earlier this -- this 3 week or late last week. I don't recall if it 4 was Friday or Monday. 5 Q. Okay. For the purposes of the 6 record, could you just identify what the 7 document is that I just handed you as 8 Plunkett Deposition Exhibit Number 1? 9 A. It's a notice of oral and 10 videotaped deposition for myself, dated -- I 11 don't see the date, but probably on the very 12 last -- do you need that or just -- is that 13 enough of an identification? 14 Q. That's all right. 15 Now, contained within the 16 deposition notice there is a reference to a 17 request for materials that are identified in 18 more detail in Schedule A. 19 Do you see that? 20 A. Yes. 21 Q. Have you reviewed Schedule A? 22 A. Yes. 23 Q. Did you bring any documents 24 with you in response to the request in 25 Schedule A?</p> |

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| <p>1 A. The only thing that I believe 2 that I had to bring that had not already been 3 provided was additional billing since the 4 time of my last deposition. 5 Q. Okay. And is it my 6 understanding that the documentation related 7 to additional billing that you have done 8 since your prior deposition was produced 9 yesterday at the deposition in the Forrest 10 case? 11 A. That's correct. 12 Q. All right. And the information 13 contained in the documents produced at the 14 Forrest deposition yesterday, do those 15 contain an up-to-date record of the billing 16 that you have submitted for your work in 17 connection with the litigation against 18 Johnson & Johnson? 19 A. Yes, with the understanding 20 that I haven't submitted a bill for December 21 yet. 22 Q. Okay. How much time have you 23 spent working in connection with your 24 opinions in the case against Johnson & 25 Johnson related to its baby powder in the</p> | <p>1 but I'll bill separately for the time I spent 2 yesterday right before the deposition and 3 then at the deposition, so... 4 Q. What did you do to prepare for 5 your deposition today? 6 A. I reviewed my reports, the 7 three reports that I filed in the litigation. 8 I had a meeting with attorneys on Monday, and 9 then we had a short meeting yesterday evening 10 because some attorneys arrived that were not 11 here on Monday. 12 And essentially went through 13 some of the documents that -- went through 14 some of the documents that I had cited in the 15 report in certain paragraphs, just to refresh 16 my memory of what they were. So if you want 17 me to tell you which paragraphs, I can do 18 that. 19 Q. I will in just a moment. Okay. 20 A. Want me to repeat that? I'm 21 sorry. 22 Q. That's all right. 23 Dr. Plunkett, you referenced 24 the fact that you reviewed specific 25 paragraphs of your expert reports in</p> |
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| <p>1 month of December? 2 A. So I'm -- on all the cases that 3 I am involved in that are pending, not just 4 this deposition? 5 Q. I'll ask first all cases and 6 then we'll narrow it to the deposition. 7 A. So in all -- 8 Q. I mean to the MDL, I'm sorry. 9 A. Okay. So in all cases this 10 month, probably eight hours so far, maybe 11 ten. 12 Q. Does that include the time that 13 you've spent attending deposition? 14 A. No, that's not including 15 yesterday's deposition time. I apologize. I 16 forgot about that. 17 Q. And how much of the eight to 18 ten hours that you have spent this month 19 working on these cases against Johnson & 20 Johnson, setting aside the time you spent in 21 deposition yesterday, relate to the MDL 22 specifically? 23 A. So it will probably be 24 billed -- it will be one bill for the 25 preparation time because the prep overlapped,</p> | <p>1 preparation for today's deposition. 2 Could you identify those 3 paragraphs for me? 4 And it's helpful to you, we can 5 go ahead and mark your three expert reports, 6 if you're referring to all three. 7 A. I'm going to refer just to the 8 MDL report because that's what we're here to 9 talk about. I mean, if you want to talk 10 about what I did to get ready for yesterday 11 separately or -- 12 MR. MEADOWS: Might be helpful 13 to go ahead and mark them. 14 MS. BRANSCOME: Why don't we go 15 ahead and just mark the three reports, 16 and then we can walk through. 17 (Plunkett Exhibits 2, 3 and 4 18 marked for identification.) 19 QUESTIONS BY MS. BRANSCOME: 20 Q. So, Dr. Plunkett, do you have a 21 copy of your three reports in front of you? 22 A. Yes, I do. 23 Q. Do those contain any markings, 24 highlightings or flags? 25 A. No, they don't.</p> |

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| <p>1 Q. Okay. Do you mind if we mark 2 your copies as the official records? 3 A. No, that's fine. 4 Q. So we will mark -- well, let's 5 do this in chronological order. So I am 6 marking as Plunkett Deposition Exhibit 7 Number 2 the expert report of Dr. Plunkett 8 dated October 5, 2016. 9 Could you confirm, 10 Dr. Plunkett, that that's what I marked as 11 Deposition Exhibit Number 2? 12 A. Yes, it is. 13 Q. And then we will mark as 14 Deposition Exhibit Number 3 supplemental 15 expert report of Dr. Laura Plunkett dated 16 August 29, 2018. 17 Dr. Plunkett, could you confirm 18 that I marked that as Exhibit Number 3? 19 A. Yes, that's correct. 20 Q. And then Exhibit Number 4, we 21 will mark the expert report dated 22 November 16, 2018, by Dr. Plunkett that was 23 produced in the MDL. 24 Could you confirm that I marked 25 that as Deposition Exhibit Number 4?</p> | <p>1 are also cited in paragraph 39 as well, some 2 of those same ones that are... 3 And then in Section 5 of my 4 report where I'm talking about exposure, I 5 looked again at Parmley and Woodruff. I 6 looked again at Vetner and Iturrulde and Egli 7 and Newton last night. 8 And the only other thing I 9 looked at is not cited in this report because 10 it came out after the report was filed, and 11 that was -- and I did bring a copy of that. 12 That was the risk assessment that was done in 13 Canada. Some people refer to it as -- by the 14 first author's last name, Taher, T-a-h-e-r. 15 And I may be pronouncing that wrong, but... 16 (Plunkett Exhibit 5 marked for 17 identification.) 18 QUESTIONS BY MS. BRANSCOME: 19 Q. All right. And I see that you 20 brought a copy of that document with you. 21 Just for the purposes of the record, let's 22 mark that as Plunkett Deposition Exhibit 23 Number 5. 24 Are there any markings, 25 highlightings or notations on that document?</p> |
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| <p>1 A. Yes, that's correct. 2 Q. All right. And so now back to 3 the question of you referenced the fact that 4 you looked at specific paragraphs of your 5 expert report in preparation for today's 6 deposition. If you could, using Deposition 7 Exhibit Number 4, identify which paragraphs 8 you looked at specifically in preparation for 9 the deposition. 10 A. So it wasn't the paragraphs. 11 There were certain documents in paragraphs, 12 so that's what I was referring to, so... 13 So starting in paragraph 38 14 where I'm talking about sort of the timeline 15 of information about human health hazards and 16 talc dust. So I just went back and refreshed 17 on a few of the older papers. 18 I looked again at the patent 19 documents that are cited in the first bullet. 20 I looked again at a paper by 21 Eberl, 1948, which is in the last bullet. 22 The patent documents are also there as well. 23 And that -- so that would be 24 all I pulled in that paragraph. 25 I believe that those documents</p> | <p>1 A. No, there's not. 2 And then the other document I 3 looked at that was not cited in the report, 4 there is a printout from the government of 5 Canada website that talks about some 6 statements on talc, and so I printed that out 7 as well. This was published at the same time 8 that the risk assessment was published. 9 (Plunkett Exhibit 6 marked for 10 identification.) 11 QUESTIONS BY MS. BRANSCOME: 12 Q. All right. We'll mark that for 13 purposes of the record as Plunkett Deposition 14 Exhibit Number 6. We might come back to 15 those documents. 16 So returning briefly to the 17 deposition notice and the requests in 18 Schedule A, the billing information you 19 produced yesterday and then we just discussed 20 additional information with respect to that, 21 are there any other documents that you have 22 in your possession that are responsive to 23 requests identified in Schedule A that have 24 not been produced? 25 A. I don't believe so, no.</p> |

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| <p>1 Everything -- I do believe that there were 2 some objections filed to this, so there's 3 some things that I did not provide based on 4 that. 5 Some of the things I don't 6 have, too. I think you asked for -- maybe 7 you didn't ask for that. Usually people ask 8 for copies of old depositions, and I don't 9 keep those. And maybe you didn't ask for 10 that, but that's usually a request. 11 Let me see. 12 Q. Okay. Now, you mentioned that 13 you met with attorneys on Monday. And who 14 was present at that meeting? 15 A. So on Monday it was 16 Mr. Meadows, sitting here. Ms. Tucker, 17 Mr. Beattie, were at the meeting on Monday. 18 Q. All right. And how long did 19 that meeting last? 20 A. Probably six hours, I guess, 21 six hours with them, and then I also did some 22 other work on my own, but... 23 Q. Okay. And then you mentioned 24 that you had another meeting last night. 25 Who was present at that</p> | <p>1 Q. All right. And then you 2 produced a supplemental report earlier this 3 year, on August 29, 2018, and that's been 4 marked as Deposition Exhibit Number 3, 5 correct? 6 A. Yes. 7 Q. When did you begin work on the 8 supplemental report that you produced at the 9 end of August in 2018? 10 A. I want to say -- let's see. I 11 want to say sometime in the summer. Maybe as 12 early as May, but I believe May -- May, June 13 time frame of 2018. 14 My billing would reflect that, 15 so, again, we can pull my billing. And I 16 would have called it preparation of the 17 supplemental report in my billing. 18 Q. Okay. Why did you choose to 19 draft a supplemental expert report? 20 A. So over the time I had worked 21 on different trials here in St. Louis 22 particularly, additional documents that were 23 not cited in my original report became 24 reliance materials based on their 25 presentation at trial. So there were enough</p> |
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| <p>1 meeting? 2 A. So that was probably about an 3 hour, and that would have been Mr. Tisi -- or 4 maybe two hours. Mr. Tisi joined us 5 yesterday afternoon. And Mr. Golomb, too, 6 I'm sorry. 7 Q. All right. Okay. Now, looking 8 at the three reports that you have produced 9 in the litigation involving Johnson's baby 10 powder, I wanted to get an understanding of 11 how those three reports relate to one 12 another. 13 So you have the first report 14 that you produced that was dated October 5, 15 2016. I believe that was originally produced 16 in the Uhl case; is that correct? 17 A. I'm not sure the name of the 18 first case, but it was in the -- some of the 19 St. Louis cases, yes. 20 Q. All right. And when did you 21 begin work on that report? 22 A. You'd have to look at my 23 billing record, which I know was an exhibit 24 to yesterday's deposition. I believe they 25 started in 2015.</p> | <p>1 of those that I thought it was important to 2 add to the original report with additional 3 documents that I had reviewed over time. 4 Since October of 2016 through, 5 let's say, the summer of 2018, there were a 6 variety of additional documents that I had -- 7 I had seen. 8 It was also my understanding 9 that during that time period Johnson & 10 Johnson had provided additional documents 11 that weren't provided or available to me in 12 2016, so additional discovery that was now 13 available to look at. So some of this is a 14 matter of additional evidence that wasn't 15 available when I wrote my initial -- my 16 initial report. 17 Q. All right. Now when you say 18 the additional documents became reliance 19 materials in trial, what do you mean by that? 20 A. So additional documents that we 21 refer to in trial that I use to support 22 opinions that weren't necessarily 23 specifically cited within the body of my 24 report or described within the body of my 25 report. They were likely on my larger</p> |

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| <p>1 reliance list, but they weren't things that</p> <p>2 were cited.</p> <p>3 In other words, if you look at</p> <p>4 my original report in -- when I say the body,</p> <p>5 the paragraphs. I always put a reference</p> <p>6 list and then I'll have Bates numbers. So</p> <p>7 during trial, things that were from my larger</p> <p>8 reliance list that weren't specifically</p> <p>9 discussed in my report became support for</p> <p>10 different opinions that -- based on questions</p> <p>11 at trial.</p> <p>12 Q. Okay. When you say these were</p> <p>13 documents that "we" refer to at trial, you're</p> <p>14 referring to yourself and attorneys</p> <p>15 representing the plaintiffs?</p> <p>16 A. Yes, that's correct.</p> <p>17 Q. Okay. And understanding that</p> <p>18 the purpose of today's deposition is focused</p> <p>19 specifically on the MDL, then you produced a</p> <p>20 report specific to the MDL on November 16,</p> <p>21 2018, that we've marked as Exhibit 4,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. When did you begin work on the</p> <p>25 report that you produced specifically in the</p> | <p>1 ask who the -- who was involved in the</p> <p>2 drafting of the report that was produced in</p> <p>3 the MDL?</p> <p>4 MR. MEADOWS: Hold on just one</p> <p>5 second.</p> <p>6 Ask the question one more time.</p> <p>7 I want to make sure we're not</p> <p>8 venturing into attorney work product</p> <p>9 realm here.</p> <p>10 QUESTIONS BY MS. BRANSCOME:</p> <p>11 Q. Dr. Plunkett, do you consider</p> <p>12 the report that you have issued in the MDL</p> <p>13 which is identified as Exhibit 4 to be</p> <p>14 attorney work product?</p> <p>15 MR. MEADOWS: Objection. Don't</p> <p>16 answer that. That calls for a legal</p> <p>17 conclusion, and at this point I'm</p> <p>18 going to instruct you not to answer</p> <p>19 questions about how the report came</p> <p>20 into be.</p> <p>21 MS. BRANSCOME: Are you</p> <p>22 instructing her to refuse to answer</p> <p>23 any questions that involve the</p> <p>24 development of her expert report?</p> <p>25 MR. MEADOWS: I'm instructing</p> |
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| <p>1 MDL?</p> <p>2 A. Sometime right after -- I would</p> <p>3 say early fall of 2018, sometime after</p> <p>4 this -- the supplemental report was filed.</p> <p>5 Probably right after that.</p> <p>6 Q. Okay. So is it fair to say</p> <p>7 that you began work on your MDL report after</p> <p>8 completing the supplemental expert report</p> <p>9 that has been marked as Exhibit 3?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. Okay. Who was involved in the</p> <p>12 drafting of the report that's been identified</p> <p>13 as Exhibit 4?</p> <p>14 MR. MEADOWS: Objection. Hang</p> <p>15 on a second.</p> <p>16 Are you asking about</p> <p>17 communications between attorneys and</p> <p>18 Dr. Plunkett?</p> <p>19 QUESTIONS BY MS. BRANSCOME:</p> <p>20 Q. Dr. Plunkett, none of the</p> <p>21 questions I will ask you here today are</p> <p>22 intended to elicit information that's</p> <p>23 protected by the attorney-client privilege.</p> <p>24 So setting that aside, anything</p> <p>25 that you understand to be privileged, I can</p> | <p>1 her not to answer your last question.</p> <p>2 QUESTIONS BY MS. BRANSCOME:</p> <p>3 Q. Are you following your</p> <p>4 attorney's instructions, Dr. Plunkett?</p> <p>5 A. Yes.</p> <p>6 MS. BRANSCOME: At this point I</p> <p>7 would like to go off the record,</p> <p>8 please.</p> <p>9 VIDEOGRAPHER: Okay. We are</p> <p>10 going off the record at 9:30 a.m.</p> <p>11 (Off the record at 9:30 a.m.)</p> <p>12 VIDEOGRAPHER: We are back on</p> <p>13 the record at 9:32 a.m.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. Dr. Plunkett, other than</p> <p>16 attorneys, if attorneys were involved -- I am</p> <p>17 not asking questions about that -- were there</p> <p>18 any individuals who assisted you in preparing</p> <p>19 the report that has been marked as Exhibit 4?</p> <p>20 A. There was no one that actually</p> <p>21 assisted in writing the report. I do -- when</p> <p>22 I did my literature searches, I had my</p> <p>23 husband help me retrieve articles that I</p> <p>24 identified for retrieval, but certainly there</p> <p>25 was no -- he doesn't participate in the</p> |

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| <p>1 actual review of articles or in drafting of</p> <p>2 the report. That's all my work.</p> <p>3 Q. Okay. And when you say that</p> <p>4 your husband retrieved articles, was this</p> <p>5 simply -- what information did you provide</p> <p>6 him in order to enable him to retrieve a</p> <p>7 particular article?</p> <p>8 A. So we use a service in Houston</p> <p>9 called Loansome Doc, which is affiliated with</p> <p>10 our local medical library system and also</p> <p>11 with the National Library of medicine and NIH</p> <p>12 libraries. So I give him an online search</p> <p>13 that I put into a clipboard. He takes that,</p> <p>14 makes the request or retrieves -- some of</p> <p>15 them will be free, and so he'll actually go</p> <p>16 to the websites for the -- and then put them</p> <p>17 into a folder for me.</p> <p>18 So he does that physical part</p> <p>19 of it through the computer, but he doesn't --</p> <p>20 he doesn't do the searches or decide which</p> <p>21 ones to retrieve. I do that.</p> <p>22 Q. Okay. Did you have any</p> <p>23 discussions with your husband about the</p> <p>24 substantive content of the report that's</p> <p>25 identified as Exhibit 4?</p> | <p>1 been marked as Exhibits 2, 3 and 4 to each</p> <p>2 other, what is your -- what is your position</p> <p>3 with respect to opinions that you have stated</p> <p>4 or language you have used in Exhibits 2 and 3</p> <p>5 that may not appear in Exhibit 4?</p> <p>6 A. I don't think I understand what</p> <p>7 your -- what you mean by my position. Are</p> <p>8 you asking --</p> <p>9 MS. PARFITT: And I'll object</p> <p>10 to that question.</p> <p>11 THE WITNESS: Are you asking me</p> <p>12 to describe -- I mean, I could</p> <p>13 describe for you the overlap. I mean,</p> <p>14 there's not complete overlap. Is that</p> <p>15 what you're asking me or --</p> <p>16 QUESTIONS BY MS. BRANSCOME:</p> <p>17 Q. I am. Why don't you take a</p> <p>18 shot at it and then I may narrow my question,</p> <p>19 but I'm just trying to understand how the</p> <p>20 reports relate to one another.</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 THE WITNESS: So they relate to</p> <p>23 each other, I would say, based on</p> <p>24 timing first, because obviously the</p> <p>25 first report was two years ago, and</p> |
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| <p>1 A. No.</p> <p>2 Q. Does he do any evaluation --</p> <p>3 for example, if you were to provide him a</p> <p>4 search and it generates multiple documents by</p> <p>5 a given author, does he identify additional</p> <p>6 articles that you might want to consider?</p> <p>7 A. Only -- he has done that, but</p> <p>8 only with the streams of letters to the</p> <p>9 editor. So I ask him always if I'm pulling</p> <p>10 an article. Happens a lot at the New England</p> <p>11 Journal of Medicine or some of the other</p> <p>12 medical journals where there's pretty active</p> <p>13 letter to the editor correspondence that</p> <p>14 happens.</p> <p>15 So I always say to him, "If</p> <p>16 there's any citation to this through the</p> <p>17 letter to the editor comments, would you</p> <p>18 please retrieve those," and so he will do</p> <p>19 that search to look for that.</p> <p>20 Q. Okay.</p> <p>21 A. And I'm not sure that that</p> <p>22 happened in any of these articles, but I'm</p> <p>23 talking my general process that we use.</p> <p>24 Q. Okay. In terms of the</p> <p>25 relationship of the three reports that have</p> | <p>1 then many more documents. So that's</p> <p>2 how the 1 and 2 relate -- or Exhibit 2</p> <p>3 and 3 relate to each other.</p> <p>4 In the MDL litigation, I was</p> <p>5 asked to address very specific topics</p> <p>6 and things because there's a -- it's a</p> <p>7 different -- I don't know all of them,</p> <p>8 but there's a different set of experts</p> <p>9 that work in different litigations.</p> <p>10 So my role in the MDL, I</p> <p>11 believe, is set out based on this</p> <p>12 report, whereas in the original</p> <p>13 reports I may have had -- I did have a</p> <p>14 broader role in some of those cases.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. Okay. Can you describe for me</p> <p>17 your understanding of your role in the MDL?</p> <p>18 A. It's my understanding that I</p> <p>19 have been asked to provide opinions related</p> <p>20 to the -- generally the toxicology of talcum</p> <p>21 powder products, including all the individual</p> <p>22 constituents that make up that product; to</p> <p>23 look historically back in time about what was</p> <p>24 known and when about the toxic effects of</p> <p>25 talc and different constituents within talc.</p> |

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| <p>1 And that was sort of the -- that's been --</p> <p>2 I consider that sort of the meat of what I've</p> <p>3 been asked to do.</p> <p>4 But separate from that, another</p> <p>5 part important part of my testimony or things</p> <p>6 I was asked to provide was an overview of the</p> <p>7 regulatory process for cosmetics and then the</p> <p>8 information that accumulated scientifically,</p> <p>9 how that related to what a company is</p> <p>10 required to do under the regulations in order</p> <p>11 to provide consumers with appropriate</p> <p>12 information about the safety of the product.</p> <p>13 So kind of the regulatory opinions, I guess</p> <p>14 you want to call it, that area.</p> <p>15 I have sections on that, and I</p> <p>16 think you can see that by the different</p> <p>17 sections in my report where I set out</p> <p>18 different general topics.</p> <p>19 And then I was also asked to</p> <p>20 address some of the issues related to how the</p> <p>21 information on the safety of talc has been</p> <p>22 disseminated publicly and also based on my</p> <p>23 review of different internal company</p> <p>24 documents, both from Johnson & Johnson -- or</p> <p>25 from Johnson & Johnson, Imerys, as well as</p> | <p>1 the companies had, in fact, influenced the</p> <p>2 regulators or PCPC?</p> <p>3 MR. MEADOWS: Objection.</p> <p>4 THE WITNESS: Not in my -- not</p> <p>5 when I first started this process. So</p> <p>6 that is -- those opinions actually go</p> <p>7 back into my original report. So</p> <p>8 that's not something, I don't believe,</p> <p>9 that was not covered in my original</p> <p>10 report or even in my supplemental</p> <p>11 report. I just have different -- some</p> <p>12 additional documents that I have</p> <p>13 reviewed.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. Okay.</p> <p>16 A. And this is something when I</p> <p>17 first evaluated the case and first started</p> <p>18 looking at the documents, those are opinions</p> <p>19 that I had formed based on my review.</p> <p>20 Certainly by the time I drafted</p> <p>21 the MDL report, I think if you listened to</p> <p>22 my -- read my trial testimony, you understand</p> <p>23 I had those opinions at the time I started</p> <p>24 writing this report.</p> <p>25 Q. Now, what I'd like to</p> |
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| <p>1 the PCPC, which is the Personal Care Products</p> <p>2 Council, formerly known as the CTFA, to look</p> <p>3 at those interactions and how those companies</p> <p>4 set about to influence the process around the</p> <p>5 safety assessment of talc over the years. So</p> <p>6 different activities that happened with</p> <p>7 respect to the IS RTP meetings in the '90s,</p> <p>8 with respect to the NTP process at different</p> <p>9 points in time.</p> <p>10 The CIR process, I think I</p> <p>11 cover, and I also talk a little bit about</p> <p>12 IARC, I believe, as well.</p> <p>13 So the interactions of the</p> <p>14 industry with the science and then how that</p> <p>15 science ends up getting described within --</p> <p>16 either to regulators or to bodies that are</p> <p>17 reviewing the science related to the</p> <p>18 products.</p> <p>19 Q. You mentioned as one of the</p> <p>20 categories that you were asked to opine about</p> <p>21 in the MDL that you were looking to set about</p> <p>22 the influence that companies may have exerted</p> <p>23 over the regulatory process or PCPC.</p> <p>24 When you began that analysis,</p> <p>25 did you start with the predicate belief that</p> | <p>1 understand next is, are there -- of the</p> <p>2 topics that you just identified that you</p> <p>3 understand that you're offering opinions</p> <p>4 about in the MDL, which, if any, of those</p> <p>5 topics are in your view new as compared to</p> <p>6 the opinions that you have offered that are</p> <p>7 contained in Exhibits 2 and 3?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 THE WITNESS: So I don't think</p> <p>10 any of the MDL opinions are new.</p> <p>11 QUESTIONS BY MS. BRANSCOME:</p> <p>12 Q. Okay.</p> <p>13 A. I think that they may have --</p> <p>14 they may -- they may cite to additional</p> <p>15 documents that haven't been cited to in the</p> <p>16 first two reports, but I believe there's a</p> <p>17 significant overlap even on the documents</p> <p>18 that are cited.</p> <p>19 Q. And you mentioned that your</p> <p>20 role in the MDL is more narrow than the role</p> <p>21 you've served in other cases.</p> <p>22 What topics have you opined</p> <p>23 about in other cases that you are not</p> <p>24 intending to opine about in the MDL?</p> <p>25 A. So I am not doing general</p> |

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| <p>1 causation in the MDL, although I am indeed</p> <p>2 providing opinions on certain aspects of the</p> <p>3 cause and effect relationship such as -- you</p> <p>4 know, I talk about biologic plausibility,</p> <p>5 underlying knowledge about different</p> <p>6 toxicities of the compounds over time, but</p> <p>7 I'm not doing a full causation analysis in my</p> <p>8 MDL report, and hopefully you see that when</p> <p>9 you read the report.</p> <p>10 Q. So as you sit here today,</p> <p>11 Dr. Plunkett, you are not intending to offer</p> <p>12 the opinion in the MDL that Johnson's baby</p> <p>13 powder causes ovarian cancer; is that</p> <p>14 correct?</p> <p>15 A. Not in those words. I think if</p> <p>16 you read my report, I talk about the</p> <p>17 fact that Johnson -- it's my opinion that</p> <p>18 Johnson's baby powder increases the risk of</p> <p>19 cancer -- ovarian cancer, which is a</p> <p>20 different assessment than the way you stated</p> <p>21 it.</p> <p>22 Q. All right. And it is -- as you</p> <p>23 sit here today, Dr. Plunkett, it is your</p> <p>24 understanding that you are not being offered</p> <p>25 to give a, as you termed it, a general</p> | <p>1 principles of, first, is there a hazard, is</p> <p>2 the first step. Is there a hazard that would</p> <p>3 be relevant to human health.</p> <p>4 Then looking at the data and</p> <p>5 determining whether that -- that body of data</p> <p>6 allows you to either quantify risk in some</p> <p>7 way or to qualitatively shows you that</p> <p>8 there's a change in risk based on exposure to</p> <p>9 the product.</p> <p>10 So your statement may be as</p> <p>11 simple as there's an increased risk, or you</p> <p>12 can take data in a risk assessment and do a</p> <p>13 quantification such as in a -- a cancer risk</p> <p>14 assessment based on an animal data set. You</p> <p>15 might actually calculate a cancer potency</p> <p>16 factor, for example. Those kinds of things.</p> <p>17 That's another application of risk</p> <p>18 assessment. Same basic process but focusing</p> <p>19 just, for example, on one study.</p> <p>20 My human health risk assessment</p> <p>21 or safety assessment, like the causation</p> <p>22 analysis, does look across all kinds of data,</p> <p>23 but my goal was not to analyze the data under</p> <p>24 the Hill considerations, which is what I</p> <p>25 would typically do, in order to go through</p> |
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| <p>1 causation opinion in the MDL, correct?</p> <p>2 A. That's my understanding, yes.</p> <p>3 Q. Now, you mentioned that the</p> <p>4 analysis as to whether a substance increases</p> <p>5 the risk of a particular outcome is different</p> <p>6 than a causation analysis.</p> <p>7 Can you explain to me what you</p> <p>8 meant by that?</p> <p>9 A. So I discussed this yesterday</p> <p>10 in my deposition. There's -- there's a</p> <p>11 process called risk assessment. Sometime --</p> <p>12 in the area of consumer products you can also</p> <p>13 refer to it as safety assessment. And then</p> <p>14 there's the process of what I call general</p> <p>15 causation analysis, or full causation</p> <p>16 analysis.</p> <p>17 So even though the types of</p> <p>18 information that are considered may overlap</p> <p>19 between those two, the outcome or the</p> <p>20 statements or the -- the way you go about</p> <p>21 assessing the information is a bit different.</p> <p>22 Q. Explain to me how they're</p> <p>23 different.</p> <p>24 A. So in a risk assessment, the</p> <p>25 process starts with setting out some basic</p> | <p>1 the process of making that final opinion that</p> <p>2 indeed baby powder -- exposure to baby powder</p> <p>3 through genital application is a cause of</p> <p>4 ovarian cancer in women. That's -- to me,</p> <p>5 that's a different way to go about thinking</p> <p>6 about the question that you have to answer.</p> <p>7 And also the -- some of the</p> <p>8 data that you evaluate is evaluated a bit</p> <p>9 differently. So, for example, in my</p> <p>10 increase -- in my issue of increased risk, I</p> <p>11 use the epidemiology as supporting evidence,</p> <p>12 but I'm really focused on -- on -- more on</p> <p>13 the underlying sort of the biologic</p> <p>14 information that we have that identifies</p> <p>15 hazard and risk. So looking at the animal</p> <p>16 data, the exposure potential for the product,</p> <p>17 and then using that along with what we know</p> <p>18 with the human experience to characterize</p> <p>19 risk.</p> <p>20 Q. Is there a different level of</p> <p>21 certainty required to render a causation</p> <p>22 opinion than to render an opinion that</p> <p>23 there's an increased risk?</p> <p>24 A. I don't know that I'd describe</p> <p>25 it quite that way but -- because to me it's a</p> |

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| <p>1 different process. I certainly have to be 2 just as certain about what I say about risk 3 when I do a risk assessment as I do about -- 4 as I do when I'm doing a causation analysis. 5 I don't -- maybe you mean 6 something else, so maybe you can -- I mean, 7 I -- I certainly use the same basic standards 8 in my mind, how I weigh evidence to do the 9 different processes, but I go about them in a 10 little bit different way when I do a risk 11 assessment versus -- versus a causation 12 analysis. 13 Q. In your view, does the strength 14 of the evidence have to be greater in order 15 to determine that an agent causes a disease, 16 for example, than it does simply to say that 17 an agent increases the risk of a particular 18 outcome? 19 MR. MEADOWS: Objection. 20 THE WITNESS: I don't think 21 I've ever thought about it that way. 22 I would say to you that strength -- 23 the strength of the association is a 24 consideration under Hill that you 25 apply the epidemiology data mainly, so</p> | <p>1 statistical test you would apply, or 2 what are you asking? 3 QUESTIONS BY MS. BRANSCOME: 4 Q. So understanding that for the 5 most part if you're looking at statistical 6 significance, you're looking whether the 7 confidence interval crosses 1. 8 Are you following? 9 A. Yes, I know that, yeah. 10 Q. All right. And so when you're 11 evaluating, though, whether a particular 12 substance, in this case Johnson's baby 13 powder, increases the risk of an outcome, 14 again, in this case ovarian cancer, would it 15 be sufficient for you if that increase was 16 .01 percent, for example? 17 MR. MEADOWS: Objection. 18 THE WITNESS: That doesn't make 19 sense to me, an increase of .01 20 percent, but maybe I can answer it 21 this way for you based on what you've 22 laid out there. 23 Certainly when I do a risk 24 assessment and I make it -- if I'm 25 going to make the conclusion that I</p> |
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| <p>1 that is a different consideration 2 under causation than you do -- as you 3 would do it in a risk assessment. 4 But the strength of the 5 evidence, it's still a judgment based 6 on your experience and training as far 7 as whether or not there is enough 8 information to be able to say that you 9 believe that there is -- enough 10 information to say that the risk is 11 increased based on that exposure and 12 those conditions and whatever the 13 toxicity profile of that compound is. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. Okay. We'll get into this more 16 a little bit later, but when you say that a 17 risk is increased, is there a threshold level 18 of increase that you need to see in order to 19 render an opinion in a court of law that an 20 agent increases the risk of a particular 21 outcome? 22 MR. MEADOWS: Objection. 23 THE WITNESS: So I need you to 24 define what you mean by threshold. 25 Are you asking me a specific</p> | <p>1 believe that it's my opinion to a 2 reasonable degree of scientific 3 certainty that exposure to baby powder 4 in women increases the risk of cancer, 5 I'm having to rely on -- I do rely on 6 data that allows me to draw 7 conclusions because either there's a 8 statistical significant finding found 9 or the -- there's a consistency among 10 the pattern of the data that shows 11 there's information that fits together 12 consistently. And maybe -- you want 13 me to explain what I mean by that? 14 No? 15 Whereas I think what you're 16 asking is when an epidemiologist 17 applies -- looks at a body of -- in a 18 causation analysis looks at a body -- 19 and I do this, too -- looks at a body 20 of epidemiological studies and you 21 weight the studies, obviously you're 22 weighting the studies differently 23 based on whether they have shown 24 statistical significance or not, 25 right?</p> |

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| <p>1 And it isn't that it's a one to 2 one. If you have one positive and one 3 negative, that isn't how you may 4 decide to finally weight that 5 evidence, but certainly you have to 6 consider whether or not what was seen 7 or reported is showing you something 8 reliable -- or you can make a 9 statement reliably about whether or 10 not that finding was biologically 11 significant. And biologically 12 significant would typically be linked 13 to a finding that has statistical 14 significance in an epi study unless 15 the study was not designed to be able 16 to answer the question properly. 17 So -- and I've discussed that a 18 little bit yesterday with Mr. Smith on 19 the issue of power to detect. So 20 that's something you do consider in 21 epi. 22 But, yes, statistical 23 significance certainly goes into your 24 weight of the evidence there. 25</p> | <p>1 company evaluating compliance with FDA 2 regulations with respect to cosmetics? 3 A. Yes. 4 Q. Okay. What is your experience 5 with respect to that? 6 A. So that's -- one of the clients 7 that I currently work for where I am asked to 8 provide input on advertising, promotion and 9 labeling of some of the products and then 10 also some of the ingredients that are being 11 promoted for use to -- to produce cosmetic 12 products. So it's the idea of providing that 13 advice over my understanding of the 14 regulations what can be said and can't be 15 said about certain ingredients. 16 This company is involved in 17 making both ingredients but also some 18 finished products now based on -- it's a 19 large company that owns a lot of little 20 subsidiaries. 21 Q. My question, though, 22 Dr. Plunkett, was, have you ever been in a 23 decision-making position for a company 24 evaluating compliance with FDA regulations 25 with respect to cosmetics?</p> |
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| <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. You talked about you're 3 intending to offer an opinion with respect to 4 what a company is required to do under the 5 regulations; is that correct? 6 A. Yes. 7 Q. Okay. What regulations are you 8 specifically referring to? 9 A. So cosmetic regulations that 10 exist within -- so it's the entire process as 11 I describe how cosmetic -- what -- are 12 cosmetics subject to regulation by FDA? Yes. 13 What are the types of things that companies 14 have to do before they're marketed, what does 15 the company have to do once the product is on 16 the market, those kinds of things. 17 Q. Have you ever worked directly 18 for any regulatory agency? 19 A. No, I have not. 20 Q. And suffice it to say you have 21 never been in a decision-making position 22 within a regulatory agency, correct? 23 A. That's correct, I have not. 24 Q. Have you ever been in a 25 decision-making position with respect to a</p> | <p>1 MS. PARFITT: Objection. Asked 2 and answered. 3 THE WITNESS: So that's what 4 I'm saying. They're relying on my 5 input to make a decision on what will 6 go in the materials. 7 QUESTIONS BY MS. BRANSCOME: 8 Q. Do you have decision-making 9 authority within that company or, as you 10 described it, are you providing advice and 11 input? 12 A. I'm providing advice, but the 13 things I'm advising on are the things that 14 happened. So in other words, they don't have 15 anybody in the company that understands the 16 process of what they can say. So I -- I 17 advise them that you need to remove this 18 language or that this is more appropriate 19 language. They make those changes, and then 20 that is what is done. 21 So I agree, I'm not an employee 22 of that company. I am a consultant working 23 with the company, but it is a little 24 different than some of the work that I do 25 where I -- what I -- the advice that I'm</p> |

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| <p>1 giving is actually something that I know 2 actually happened. Sometimes you give advice 3 to companies, but it doesn't -- we have no 4 idea whether the company actually follows our 5 advice. 6 Q. My question is slightly 7 different, Dr. Plunkett. 8 If you were to give advice to 9 the company that you've referenced as having 10 experience with cosmetic regulation 11 compliance that that company chose not to 12 follow, that company has the ability to 13 ignore your advice, correct? 14 A. Yes, I would imagine that they 15 could do that. 16 Q. Okay. Have you ever drafted 17 regulations that relate to cosmetics? 18 A. Actually drafted a regulation? 19 No, I have not. 20 Q. All right. You reference in 21 your report language out of 21 CFR 740.1, and 22 specifically -- you reference it in a few 23 places. And I can direct you specifically to 24 paragraph 22 in Exhibit 4. 25 A. Yes. I'm there.</p> | <p>1 A. So it's -- first off, you would 2 use the common English language definition. 3 I don't believe that those -- I haven't seen 4 a definition separate within the regulations. 5 Sometimes there will be. 6 So based on that and my 7 experience and the looking into what others 8 have described about this, this is the idea 9 of considering how the product is used, is 10 one of the -- one of the concerns that you 11 have, and whether or not the -- based on how 12 the product is used and how the product is 13 being sold, that in order to prevent a health 14 hazard, a warning hazard -- a warning 15 statement would be needed. 16 Q. Can you cite to me any language 17 within the regulation or even supporting 18 documentation, a comment, something of that 19 nature, that would define "whenever necessary 20 or appropriate" with respect to how the 21 product is used? 22 MS. PARFITT: Objection. 23 THE WITNESS: I don't think I 24 understand your question. 25 Are you asking me to cite to a</p> |
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| <p>1 Q. All right. And do you see here 2 you have replicated language from 21 CFR 3 740.1 that reads, "The label of a cosmetic 4 product shall bear a warning statement 5 whenever necessary or appropriate to prevent 6 a health hazard that may be associated with 7 the product"? 8 Do you see that? 9 A. Yes. 10 Q. And you added emphasis on 11 particular portions of this sentence, 12 correct? 13 A. Yes, I did that, exactly. 14 Q. All right. Now there's a 15 clause in this sentence that states, 16 "Whenever necessary or appropriate." 17 Do you see that? 18 A. Yes. 19 Q. You did not emphasize that 20 language; is that correct? 21 A. That's correct, I did not. 22 Q. What is your understanding 23 as -- what you describe as an FDA regulatory 24 specialist of the meaning of "whenever 25 necessary or appropriate" in 21 CFR 740.1?</p> | <p>1 reference or a part of the regulation 2 where they explain it, or what are you 3 asking me? Guidance document or -- 4 QUESTIONS BY MS. BRANSCOME: 5 Q. Yes. Can you point me to 6 anything other than your personal view of the 7 interpretation of this language that would 8 tie the requirement "whenever necessary or 9 appropriate" to how a product is used? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: I'll have to go 12 look for you whether there's a 13 guidance that states it that way. 14 This is based on my experience in 15 dealing with the products in the past. 16 I think that's also consistent 17 with what is described, I would say to 18 you, within -- it's consistent -- what 19 I'm describing to you, it's consistent 20 as well with how the CIR standard for 21 safety assessment is done, looking at 22 the issue of the -- of the -- of the 23 use. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. When you say that you're basing</p> |

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| <p>1 your interpretation of the clause "whenever 2 necessary or appropriate" on your personal 3 experience, can you point me to something 4 specific? 5 MS. PARFITT: Objection. 6 THE WITNESS: Are you asking 7 me -- are you asking me if I've ever 8 had a company that I worked for that 9 that particular clause in here was 10 extremely important to how we 11 interpreted it? I don't think I can 12 point you to that. I don't recall 13 ever having to do that specifically. 14 Or is it something different 15 you're asking me? 16 QUESTIONS BY MS. BRANSCOME: 17 Q. Dr. Plunkett, I asked you what 18 your basis was for interpreting the language 19 "whenever necessary or appropriate" means 20 that it's related to how a product is being 21 used, and the answer that you provided was 22 that it was based off of your personal 23 experience. 24 So I'm asking you, what is that 25 personal experience that gives you the basis</p> | <p>1 look at my documents in order -- the 2 first part of your question, I'd have 3 to go back and look. Off the top of 4 my head, I can't tell what I would 5 point you to. 6 On the second one, I think I 7 was telling you, is I don't -- I've 8 never -- I don't have a client that 9 I've worked for where that part of the 10 language was the only issue that I had 11 to deal with when I'm looking at 12 whether or not the product needs a 13 warning or not. 14 So typically -- I'm just 15 telling you that when I have looked at 16 labeling for products and looked at 17 the issue of does it need a warning 18 statement, when I'm reading it as 19 "whenever necessary or appropriate," 20 I'm looking at whether or not the 21 ingredient that I'm concerned about 22 within the product, how that is used 23 or what the exposure pattern would be, 24 route of exposure, how those things 25 might relate to how I would assess the</p> |
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| <p>1 for that specific interpretation? 2 MR. MEADOWS: Objection. 3 MS. PARFITT: Objection. 4 THE WITNESS: So it's in my 5 experience in dealing with companies 6 that make products and what types of 7 warnings are put or not put onto -- or 8 not -- or on labeling. So I don't 9 know how else to answer it other than 10 that. 11 I can go back and look at the 12 guidance documents to see if that is 13 described in another way, but I don't 14 recall that. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. So as you sit here today, 17 you're not able to provide me either with a 18 third-party document or an independent 19 document interpreting "whenever necessary or 20 appropriate" as you've suggested today, nor 21 can you give me specific example from your 22 personal experience; is that correct? 23 MS. PARFITT: Objection. 24 THE WITNESS: Well, I 25 certainly -- I'd have to go back and</p> | <p>1 safety issue at hand. And so that's 2 what I'm trying to tell you. 3 QUESTIONS BY MS. BRANSCOME: 4 Q. Okay. You also have -- 5 changing topics a little bit, in this -- in 6 your report marked as Exhibit 4, if you could 7 turn to paragraph 10. 8 On page 7, you state on the 9 first paragraph on page 7, "In other 10 instances I have directed others to perform 11 searches on my behalf," and this is with 12 respect to identifying documents for review 13 in forming your opinions. 14 What did you mean by that? 15 A. So in addition to doing my own 16 searches of the database, sometimes I -- I 17 have called the attorney's office and asked 18 them to -- to do a search for certain things 19 that I'm looking for to add to. So in other 20 words, I have a document I've identified. 21 I'm looking for other documents like that in 22 the large millions and millions of documents 23 that are available. And so sometimes I will 24 ask attorneys to do -- to look in the 25 database for other documents like the ones</p> |

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| <p>1 that I've identified.</p> <p>2 Q. And without getting into</p> <p>3 anything that would be -- that would call for</p> <p>4 information protected by the attorney/client</p> <p>5 privilege or attorney work product, what</p> <p>6 percentage of the overall searches for</p> <p>7 relevant documents from these particular</p> <p>8 databases that are discussed in paragraph 10</p> <p>9 would you say that you have done yourself as</p> <p>10 opposed to directed others to do?</p> <p>11 A. Well, initially when I first</p> <p>12 started searching, those were my own searches</p> <p>13 exclusively. I would say that more recently,</p> <p>14 in the last year, since I haven't added any</p> <p>15 real new areas but there's new documents that</p> <p>16 have become available, so anything -- any of</p> <p>17 the searches probably in the last year that</p> <p>18 dealt with new discovery that was produced, I</p> <p>19 would have asked the attorneys to do some of</p> <p>20 the searching in that for me. Like I'm</p> <p>21 looking for documents that are similar to</p> <p>22 this document that I cited in my original</p> <p>23 report around this same frame that may be</p> <p>24 discussing this same topic area.</p> <p>25 So in the last year I have</p> | <p>1 A. So that might cross over into</p> <p>2 work product because it's not my database,</p> <p>3 but I don't know how to answer that. I mean,</p> <p>4 I'm sure -- it's very possible that in the</p> <p>5 database you can track that, but I -- I don't</p> <p>6 know.</p> <p>7 MR. MEADOWS: Okay.</p> <p>8 THE WITNESS: I don't have</p> <p>9 anything saved on my computer that</p> <p>10 way, but when you go to the database</p> <p>11 itself, it's possible you could track</p> <p>12 that. I just don't have a record on</p> <p>13 my computer in my office.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. When you made the decision at</p> <p>16 some point in time -- it may have been even</p> <p>17 prior to you issuing your first report --</p> <p>18 that you wanted to look at company documents,</p> <p>19 did you set out specific categories of</p> <p>20 documents that you wanted to review?</p> <p>21 A. Not so much categories but key</p> <p>22 words. So -- and areas. I guess areas is</p> <p>23 what I -- yes, I was focusing, for example,</p> <p>24 in my initial report on documents that</p> <p>25 described what was known -- what the company</p> |
| Page 55 | Page 57 |
| <p>1 asked them to do that more than I have done</p> <p>2 it, but initially it was what I did</p> <p>3 initially.</p> <p>4 Q. Okay. Do you keep any records</p> <p>5 of the various document searches either that</p> <p>6 you have performed or you have asked to be</p> <p>7 performed?</p> <p>8 A. No, I don't. My record would</p> <p>9 be -- the initial -- the record would have</p> <p>10 been what I listed in my reliance list for</p> <p>11 you in the initial report, but since then it</p> <p>12 would just be what is going to be changing</p> <p>13 within my reliance list, looking at</p> <p>14 additional documents. That's the only way I</p> <p>15 could identify for you. That would be my --</p> <p>16 my trail to know what was new and what was</p> <p>17 not.</p> <p>18 Q. My question is slightly</p> <p>19 different. Understanding that you have</p> <p>20 provided to some extent a record of the</p> <p>21 documents, my question is: Do you have any</p> <p>22 type of record for the nature of the</p> <p>23 searches, what it was that you set out to</p> <p>24 identify in the database and how did you go</p> <p>25 about finding those documents?</p> | <p>1 was discussing about cancer, ovarian cancer,</p> <p>2 cancer generally. So that was a key word</p> <p>3 used.</p> <p>4 And then I also was linking</p> <p>5 that in different searches with different</p> <p>6 time periods such as the NTP review process</p> <p>7 and dates. You can, you know, narrow down by</p> <p>8 dates or by the CIR process. Those kinds of</p> <p>9 things.</p> <p>10 So I did start with that,</p> <p>11 trying to understand what -- what is -- what</p> <p>12 was in the company files or in the files I</p> <p>13 had access to, the database, that dealt with</p> <p>14 those kinds of things because those aren't</p> <p>15 things that I could get to publicly.</p> <p>16 Obviously in the literature. So I had to --</p> <p>17 if I wanted to understand what the company</p> <p>18 knew, I had to go into their database to find</p> <p>19 out, you know, what they knew -- what they</p> <p>20 knew or were discussing over time about the</p> <p>21 ovarian cancer issue or about asbestos in</p> <p>22 talc or about CIR process, things like that.</p> <p>23 Q. Using the reports that you have</p> <p>24 produced, Exhibits 2, 3 and 4, really, and</p> <p>25 the full -- the entirety of the materials</p> |

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| <p style="text-align: right;">Page 58</p> <p>1 that you have produced in the MDL, is there 2 any way that someone reviewing those 3 documents, and those documents alone, could 4 replicate the searches that you have 5 conducted in the company databases? 6 MR. MEADOWS: Objection. 7 THE WITNESS: I don't know. 8 That's a good question. I've never 9 thought about whether you could 10 replicate or not. 11 I mean, I think I've told you 12 what I did. My strategy was to focus 13 on topic areas. So I think you 14 might -- by topic areas, if you use 15 the same kinds of topics areas as 16 described, I think you would come up 17 with documents that -- what it focused 18 down to. 19 For example, I also would 20 sometimes, as linking those words, I 21 might put in J&J documents only or 22 Imerys documents only, because the 23 database has a variety -- and the 24 PCPC. There's some different ways by 25 the Bates numbers that you can</p> | <p style="text-align: right;">Page 60</p> <p>1 reliance list, that you read, but then once 2 you started reading decided weren't relevant 3 to the opinions that you were offering? 4 A. I would have to look to answer 5 that for you. I don't know. If you want me 6 to do that, I'd have to look. 7 Q. I ask you more as a process 8 matter. 9 A. Oh. 10 Q. If you pull an article and you 11 start reading it and you realize that it is 12 not relevant to the opinions that you offered 13 in this case, the example that you just gave, 14 is it something that you would include in 15 your reliance list? 16 A. Yes, I -- I have given you 17 everything I retrieved. So if I retrieved 18 it, you would have, yes, absolutely. 19 Q. Okay. So it's fair to say of 20 the articles that are on your reliance list, 21 you could not say as you sit here today that 22 you have read each and every word of each and 23 every one of them, correct? 24 A. That's correct. And I could 25 probably tell you -- I could give you a</p> |
| <p style="text-align: right;">Page 59</p> <p>1 segregate documents as well. But I 2 don't know other than that. That's 3 all I can tell you. 4 QUESTIONS BY MS. BRANSCOME: 5 Q. You would agree with me that 6 your report does not contain a complete 7 explanation of the process by which you 8 identify company documents to review, 9 correct? 10 A. I haven't laid out my search 11 structure, that is true. 12 Q. All right. Now, the articles 13 that you have listed on your reliance list, 14 have you read each and every one of those 15 articles? 16 A. Unfortunately, yes, over time I 17 have. Some of them I have only read parts of 18 them. For example, if I started reading a 19 document and I felt that it was something I 20 pulled that really wasn't directly on point 21 for an area I'm covering, I may not have read 22 every word, but certainly I have been through 23 each of those, yes. 24 Q. Are there any articles in your 25 reliance list, that you maintained on your</p> | <p style="text-align: right;">Page 61</p> <p>1 little guidance in that possibly if I went to 2 my list, I could try to pull some out that I 3 recognize, but that's all I would be able to 4 do for you. 5 Q. Okay. How did you go about 6 identifying what articles you wanted to 7 review in forming your opinions in the MDL? 8 A. So first off, I went back to 9 what I already had. So my MDL report is a -- 10 is a compilation of a lot of material that's 11 in my first few reports. That was the basis 12 for some of the things that went into it. 13 So I didn't -- I did do, 14 though, a updating on literature searches for 15 the MDL report, looking for anything new, for 16 example, in the area, especially the area of 17 cancer data or reports of dealing with 18 ovarian cancer either -- or any articles 19 dealing with the link between inflammation 20 and cancer, ovarian cancer, generally. 21 That's one of the areas I updated looking at. 22 And then I did -- I don't think 23 I did any large, new searches, however, 24 because honestly the areas covered here are a 25 little narrower than what was covered here.</p> |

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| <p>1 I don't believe that there was any from the</p> <p>2 published -- the publicly available medical</p> <p>3 literature. There wasn't a need to do a</p> <p>4 whole new area of search. It was more</p> <p>5 updating the things that I've done in the</p> <p>6 past.</p> <p>7 So it's a real easy search to</p> <p>8 update because you can just put in talc and</p> <p>9 cancer and just look at -- get lots, but you</p> <p>10 can then just start chronologically and look</p> <p>11 what was published in the last year, for</p> <p>12 example.</p> <p>13 Q. Okay. Earlier when we were</p> <p>14 discussing the fact that you in some</p> <p>15 instances have asked your husband to pull</p> <p>16 articles, have you maintained any records of</p> <p>17 the searches that you have done with respect</p> <p>18 to scientific literature, including the</p> <p>19 searches that you have asked your husband to</p> <p>20 do?</p> <p>21 A. I have not. It's possible that</p> <p>22 there are records on billing from the library</p> <p>23 that tells you how many I ordered at</p> <p>24 different times, but that is the only</p> <p>25 records, because we do have to pay the</p> | <p>1 referring to the reliance list, are you</p> <p>2 referring to the list of articles that begins</p> <p>3 on page 40 of Exhibit 4, or is there a</p> <p>4 separate document?</p> <p>5 A. There's a separate document.</p> <p>6 So it -- that's -- I usually call reliance</p> <p>7 list the separate document. I call this</p> <p>8 references cited. So I apologize for that</p> <p>9 confusion.</p> <p>10 So these, I have read every</p> <p>11 word. If it's in my reference list, those</p> <p>12 are not an issue of not having read every</p> <p>13 word, and these should all be cited somewhere</p> <p>14 in the report.</p> <p>15 Q. Okay. If you could turn to</p> <p>16 paragraph 21 in your initial report.</p> <p>17 A. Yes, I'm there.</p> <p>18 Q. Okay. So we're looking at</p> <p>19 paragraph 21 in Exhibit 2. This is on</p> <p>20 page 10.</p> <p>21 Do you see there is a sentence</p> <p>22 here that refers to -- it's referring</p> <p>23 generally to the topic of the ability of talc</p> <p>24 to migrate from the site of application to</p> <p>25 the ovaries.</p> |
| Page 63 | Page 65 |
| <p>1 library for the retrieval.</p> <p>2 Q. Okay. And if I understood what</p> <p>3 you said earlier correctly, you indicated</p> <p>4 that any article you have ever pulled for</p> <p>5 review, you have listed on your reliance</p> <p>6 list; is that correct?</p> <p>7 A. Yes. And when I -- and let's</p> <p>8 just make sure we're talking about the same</p> <p>9 thing.</p> <p>10 So, you know, in my reports I</p> <p>11 typically have articles cited in the report</p> <p>12 separate from the reliance list. So I'm</p> <p>13 talking about the reliance list, right?</p> <p>14 Okay.</p> <p>15 So -- because I do -- I do</p> <p>16 usually -- I don't know whether I did that in</p> <p>17 this report, but I typically have a list of</p> <p>18 articles cited at the back called references,</p> <p>19 that is, things that you're actually seeing</p> <p>20 in the report body, and then there should be</p> <p>21 a separate reliance list sent to you as an</p> <p>22 appendix. I don't know what the appendix</p> <p>23 was.</p> <p>24 Q. Well, so then let's clarify</p> <p>25 that. So, Dr. Plunkett, when you're</p> | <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And then the next sentence</p> <p>4 states, "This issue was discussed by</p> <p>5 scientific and regulatory bodies that review</p> <p>6 the toxicokinetics of talc."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And in parentheses it</p> <p>10 identified EPA 1992, IARC 2010, and CIR 2013.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And then if you could</p> <p>14 turn to Exhibit 4, which is your MDL report,</p> <p>15 at paragraph 43. It's on page 28.</p> <p>16 Are you with me?</p> <p>17 A. Yes, I am.</p> <p>18 Q. You see that the exact same</p> <p>19 sentence appears -- well, not the exact same.</p> <p>20 It's been slightly modified to combine the</p> <p>21 first two sentences. But here you cite only</p> <p>22 to EPA 1992 and IARC 2010.</p> <p>23 Why did you remove CIR 2013?</p> <p>24 A. Because of my further</p> <p>25 evaluation since my initial report in 2016 of</p> |

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| <p>1 the process that was involved in the drafting</p> <p>2 of the CIR and the actual production of the</p> <p>3 report.</p> <p>4 Q. Is it your position that the</p> <p>5 migration of talc was not evaluated as part</p> <p>6 of CIR 2013?</p> <p>7 A. No. That's not my position,</p> <p>8 no.</p> <p>9 Q. Okay. And so would the</p> <p>10 sentence that's contained in paragraph 43 in</p> <p>11 Exhibit 4, which is your MDL report, if you</p> <p>12 cited to CIR 2013 in the parenthetical there,</p> <p>13 would that not be an accurate citation?</p> <p>14 A. I believe it would not be an</p> <p>15 accurate citation because I have formed</p> <p>16 opinions about the reliability of that</p> <p>17 document at this point in time.</p> <p>18 So it has to do with -- I'm</p> <p>19 citing to authorities here that I believe are</p> <p>20 reliable as far as the discussion that I see,</p> <p>21 and it's a different -- I have a different</p> <p>22 opinion now about the CIR report, which I lay</p> <p>23 out in pretty detail, I think.</p> <p>24 In fact, if you go to my</p> <p>25 section following this now in -- you'll</p> | <p>1 another question. In paragraph 43, you added</p> <p>2 two studies from your prior -- that were --</p> <p>3 that did not appear in your prior report, and</p> <p>4 it was Gardner 1981 and Edelstam 1997. This</p> <p>5 related to animal studies showing that in</p> <p>6 some species talc can migrate from the lower</p> <p>7 to the upper genital tract?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Were those studies that</p> <p>10 you were aware of before drafting your prior</p> <p>11 reports?</p> <p>12 A. I don't know that they -- I</p> <p>13 can't answer that without looking at my</p> <p>14 reliance materials for the original report.</p> <p>15 I did identify additional articles, and</p> <p>16 there's also additional articles cited here</p> <p>17 in earlier paragraph 43 that were not cited</p> <p>18 in my original report as well. I don't think</p> <p>19 I had the -- the Kunz article then cited.</p> <p>20 I'd have to go back and look.</p> <p>21 So it's possible that they were</p> <p>22 in my -- when I say my reliance materials, my</p> <p>23 original report also had a larger list of</p> <p>24 literature I didn't cite. So I'd have to</p> <p>25 look. I can't tell you whether I had them or</p> |
| Page 67 | Page 69 |
| <p>1 understand one of the issues I had was the --</p> <p>2 the difference in the evidence that was</p> <p>3 actually available once you dig into it a</p> <p>4 little further versus what they actually</p> <p>5 reviewed. That's one of the issues.</p> <p>6 Q. And I'll follow up with some</p> <p>7 more questions about the CIR, but my question</p> <p>8 here is, the sentence in your report simply</p> <p>9 states, "The migration of talc internally</p> <p>10 after perineal application was discussed by</p> <p>11 scientific and regulatory bodies that review</p> <p>12 the toxicokinetics of talc."</p> <p>13 Would it be inaccurate to say</p> <p>14 that as part of the CIR 2013 process that</p> <p>15 body did, in fact, discuss the migration of</p> <p>16 talc internally after perineal application?</p> <p>17 A. It is true that they did</p> <p>18 discuss it. I just have an issue with the</p> <p>19 reliability of their findings.</p> <p>20 Q. And so you made the decision to</p> <p>21 just remove it from the citation; is that</p> <p>22 correct?</p> <p>23 A. Yes, at this point -- at this</p> <p>24 point, at this report, that's exactly right.</p> <p>25 Q. All right. And then I had</p> | <p>1 I did not.</p> <p>2 Q. Okay. With respect to Edelstam</p> <p>3 1997 study, do you happen to know the title</p> <p>4 of that article? Even an approximation would</p> <p>5 work.</p> <p>6 A. It'll be -- should be back</p> <p>7 here. Just a second. If it's not here,</p> <p>8 that's a mistake.</p> <p>9 Oh, here it is. "Retrograde</p> <p>10 migration of starch in the genital tract of</p> <p>11 rabbits."</p> <p>12 Q. So you are citing that article</p> <p>13 for the proposition that animal studies have</p> <p>14 demonstrated that talc can migrate from the</p> <p>15 lower to upper genital tract?</p> <p>16 A. Yes, I'm citing it because it's</p> <p>17 relevant to the issue of particle migration,</p> <p>18 which talc is a particle. So, yes, that's</p> <p>19 correct.</p> <p>20 Q. Okay. But that study did not</p> <p>21 specifically deal with talc migration,</p> <p>22 correct?</p> <p>23 A. No. Well, it -- it's relevant</p> <p>24 to talc migration, but you're exactly right,</p> <p>25 they looked at the starch migration, yes. Or</p> |

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| <p>1 particles that were starch, yes.</p> <p>2 Q. We'll cover this in more</p> <p>3 detail, but is it your opinion that all</p> <p>4 particles have similar characteristics with</p> <p>5 respect to their ability to migrate in the</p> <p>6 genital tract?</p> <p>7 A. It's my -- I don't know if I'd</p> <p>8 state it quite that way. What I would say is</p> <p>9 that the evidence shows that particles</p> <p>10 generally have the ability to move up the</p> <p>11 reproductive tract in women, yes, and that if</p> <p>12 a particle is one that is similar to talc or</p> <p>13 some of the other ones where the information</p> <p>14 has been collected, I would characterize that</p> <p>15 as being within that, quote/unquote,</p> <p>16 relevance of particles.</p> <p>17 That doesn't mean all</p> <p>18 particles, but certainly in the ones that I</p> <p>19 have looked at and the data I've relied upon,</p> <p>20 there's a variety of different types of</p> <p>21 particles or substances that have been</p> <p>22 studied and shown to be able to migrate.</p> <p>23 Q. So let's take Edelstam 1997 as</p> <p>24 an example.</p> <p>25 Did you do any analysis that</p> | <p>1 genital tract?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 THE WITNESS: Again, I haven't</p> <p>4 done an in-depth analysis. I mean, as</p> <p>5 a toxicologist, there are differences</p> <p>6 between starch and talc, absolutely.</p> <p>7 For example, starch would -- I would</p> <p>8 expect to be more easily solubilized</p> <p>9 within fluids, and so that could</p> <p>10 affect the ability of them to actually</p> <p>11 not migrate as well as a talc</p> <p>12 particle, which would be less soluble</p> <p>13 than the starch would be.</p> <p>14 And there's -- I even --</p> <p>15 there's a paper I have in here, and I</p> <p>16 can look for it if you want, that</p> <p>17 talks about that difference, and it's</p> <p>18 one of the issues of cornstarch versus</p> <p>19 talc, on whether or not you would</p> <p>20 expect to get the long-term chronic</p> <p>21 responses with the difference between</p> <p>22 those two substances.</p> <p>23 So I do think there's</p> <p>24 difference, absolutely, as</p> <p>25 toxicologists generally. And the only</p> |
| Page 71 | Page 73 |
| <p>1 you can point me to that establishes that</p> <p>2 starch would have a similar migration pattern</p> <p>3 as talc?</p> <p>4 A. So I would say that the paper</p> <p>5 itself shows -- talks about the movement of</p> <p>6 starch, but are you asking something</p> <p>7 different?</p> <p>8 Are you asking me have I done a</p> <p>9 specific analysis of any differences that may</p> <p>10 occur between the migration pattern of starch</p> <p>11 and talc? Is that what you're asking me?</p> <p>12 Q. That is what I'm asking you.</p> <p>13 A. I certainly didn't do an</p> <p>14 in-depth analysis of the differences, no, but</p> <p>15 based upon my review of the literature, I</p> <p>16 believe that that paper is relevant to the</p> <p>17 overall question of migration of particulate</p> <p>18 through the reproductive tract, including</p> <p>19 particles of talc.</p> <p>20 Q. Regardless of whether or not it</p> <p>21 was an in-depth analysis, can you point me to</p> <p>22 anything other than just your belief after</p> <p>23 having read these articles that starch and</p> <p>24 talc would have similar migratory</p> <p>25 characteristics in the human or animal</p> | <p>1 reason I'm citing this paper is</p> <p>2 because I'm trying to be complete</p> <p>3 about people that have looked at this</p> <p>4 issue. And certainly it was a study</p> <p>5 that looked at this issue and talks</p> <p>6 about the movement.</p> <p>7 But I wouldn't expect starch</p> <p>8 and the talc to have the same</p> <p>9 liabilities, and I also wouldn't</p> <p>10 expect them to move exactly the same</p> <p>11 speed maybe. That's very true.</p> <p>12 QUESTIONS BY MS. BRANSCOME:</p> <p>13 Q. So you would agree with me that</p> <p>14 Edelstam is not a study demonstrating that</p> <p>15 talc can migrate from the lower to upper</p> <p>16 genital tract, correct?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: I wouldn't say it</p> <p>19 that way. What I would say instead is</p> <p>20 that Edelstam is a study that forms</p> <p>21 the overall weight of the evidence for</p> <p>22 the ethics -- for the studies that are</p> <p>23 available that address the issue of</p> <p>24 migration, but certainly it is not</p> <p>25 studying talc. So I don't disagree</p> |

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| <p>1 with you there.</p> <p>2 Unfortunately, the majority of</p> <p>3 the information that I have relied</p> <p>4 upon, and others such as the FDA in</p> <p>5 making their statements about</p> <p>6 migration, is not all directed studies</p> <p>7 just to talc. It's looking at the</p> <p>8 issue of particle movement.</p> <p>9 QUESTIONS BY MS. BRANSCOME:</p> <p>10 Q. Now, in terms of doing your</p> <p>11 risk assessment -- well, let me get back. We</p> <p>12 covered this earlier, and I want to return to</p> <p>13 it for a moment. Just to confirm: For your</p> <p>14 work in the MDL, you did not do a Bradford</p> <p>15 Hill analysis, correct?</p> <p>16 A. I did not sit down and do a</p> <p>17 Bradford Hill analysis when I started writing</p> <p>18 this report. I have done a Bradford Hill</p> <p>19 analysis in the past, which is in my original</p> <p>20 reports, but I certainly did not redo a</p> <p>21 Bradford Hill when I sat down to draft my MDL</p> <p>22 report, that is true.</p> <p>23 Q. Okay. Let me be more precise.</p> <p>24 In the report that you have</p> <p>25 produced that contains a description of your</p> | <p>1 assessment.</p> <p>2 Q. Okay. What publication would</p> <p>3 you direct me to that has used the same</p> <p>4 methodology that you have used to reach your</p> <p>5 opinions in Exhibit 4?</p> <p>6 A. I think I cite you to -- cite</p> <p>7 you to some of those. You could -- well, the</p> <p>8 directly relevant one would be looking at the</p> <p>9 chapter on risk -- toxicology in the</p> <p>10 reference manual on scientific evidence.</p> <p>11 You can also go to the NRC</p> <p>12 report where they -- it lays out the</p> <p>13 different steps that you use when you kind of</p> <p>14 break data apart into exposure versus</p> <p>15 response information.</p> <p>16 And then I cite to -- there are</p> <p>17 some guidance documents that I cite to, and</p> <p>18 this is in paragraph 13. And I'd have to</p> <p>19 pull them out again to tell you which ones</p> <p>20 relate to different pieces because some of</p> <p>21 these are -- some of these documents are</p> <p>22 specific to only, for example, maybe one part</p> <p>23 of what I did.</p> <p>24 But certainly the risk</p> <p>25 assessment process at IARC is -- they do what</p> |
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| <p>1 opinions in the MDL, you have not set forth a</p> <p>2 Bradford Hill analysis in that document which</p> <p>3 is identified as Exhibit 4, correct?</p> <p>4 A. That is true, yes.</p> <p>5 MS. PARFITT: Objection.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. And in fact, the paragraph that</p> <p>8 you -- or paragraphs that you have in your</p> <p>9 prior reports that reference a Bradford Hill</p> <p>10 analysis, those have not -- those have</p> <p>11 actually not been replicated in any form in</p> <p>12 Exhibit 4, correct?</p> <p>13 A. Yes, because, again, it was not</p> <p>14 my role to do general cause.</p> <p>15 Q. Okay. So then when we look at</p> <p>16 the methodology that you employed in reaching</p> <p>17 your opinions that are contained here in</p> <p>18 Exhibit 4, how would you characterize the</p> <p>19 methodology?</p> <p>20 A. As I have in the report. I</p> <p>21 talk about it being a risk assessment or a</p> <p>22 safety assessment, that you could use those</p> <p>23 terms interchangeably here. And then I've</p> <p>24 also used a weight of the evidence as a tool</p> <p>25 to go through the different steps of the risk</p> | <p>1 I call a hazard assessment. They identify</p> <p>2 hazard and they couldn't quantify risk, but</p> <p>3 the steps they go through are essentially the</p> <p>4 same types of steps that I went through as</p> <p>5 far as gathering data on not just response</p> <p>6 but also the potential for exposure and how</p> <p>7 that relates to the response.</p> <p>8 And then also the data that</p> <p>9 I've collected on the biologic effects of</p> <p>10 talc, toxicology of talc, are also discussed</p> <p>11 within that document as well.</p> <p>12 Q. Okay. Focusing specifically on</p> <p>13 the weight of the evidence tool, as you</p> <p>14 describe it, is there a particular document</p> <p>15 or publication that I would go to that could</p> <p>16 lay out the same process that you used for</p> <p>17 how you weighted certain pieces of evidence?</p> <p>18 A. So the documents that I've</p> <p>19 cited for you in paragraph 13 talk about what</p> <p>20 weight of the evidence is generally, but if</p> <p>21 you read what it is, it's essentially a</p> <p>22 process that each scientist brings their</p> <p>23 experience, training and judgment to.</p> <p>24 So I try to lay out for you in</p> <p>25 my discussion of the literature my thought</p> |

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|---|---|
| <p>1 process as I review each piece of</p> <p>2 information, and that is what you do as part</p> <p>3 of weight of the evidence. You gather all of</p> <p>4 the relevant information that you can find</p> <p>5 that address the question you're trying to</p> <p>6 answer, and since I'm looking at both</p> <p>7 exposure and response, I gather different</p> <p>8 pools of information.</p> <p>9 Q. You would agree that there are</p> <p>10 ways to do a weight of the evidence</p> <p>11 assessment of published literature that</p> <p>12 assign, for example, quantitative values to</p> <p>13 particular pieces of evidence, correct?</p> <p>14 A. Certain individuals have put</p> <p>15 together, but there's no one general accepted</p> <p>16 process that everyone uses. So I -- that's</p> <p>17 the issue. Again, there are certain --</p> <p>18 certain cases where I've seen that done, and</p> <p>19 then there are many -- most cases that it's</p> <p>20 not what's done.</p> <p>21 Q. Okay.</p> <p>22 A. Another body, by the way, that</p> <p>23 I -- it's new. It's not in paragraph 13. I</p> <p>24 just want to make sure I tell you that so</p> <p>25 we're clear. If you look at the Canadian</p> | <p>1 Q. Okay. As you were forming your</p> <p>2 opinions, Dr. Plunkett, about whether or not</p> <p>3 there is a risk associated with the use of</p> <p>4 Johnson's baby powder with respect to ovarian</p> <p>5 cancer, how do you keep track of the pieces</p> <p>6 of scientific evidence that you have reviewed</p> <p>7 and the respective weight that you give to</p> <p>8 them?</p> <p>9 Presumably you did not read</p> <p>10 everything in one day, for example?</p> <p>11 A. No. That's correct. So I</p> <p>12 typically will -- I typically will save the</p> <p>13 papers -- when I read the papers, I will</p> <p>14 often highlight in yellow information that I</p> <p>15 think is going to -- will be extremely</p> <p>16 relevant. I don't put notes on the document.</p> <p>17 I highlight in yellow on the PDF file to use</p> <p>18 that to write.</p> <p>19 And I also start drafting</p> <p>20 report very early, which then gets</p> <p>21 overwritten and actually ends up looking like</p> <p>22 an outline that eventually becomes the</p> <p>23 report.</p> <p>24 So one of the ways I keep track</p> <p>25 of things is I may put a paragraph name that</p> |
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| <p>1 document, they also -- in fact, a lot of what</p> <p>2 they have, you'll see the same literature</p> <p>3 described within my assessment as well.</p> <p>4 Q. So using the Canadian</p> <p>5 assessment as an example, for instance, in</p> <p>6 that assessment there were actually values</p> <p>7 assigned to particular pieces of literature,</p> <p>8 correct?</p> <p>9 A. Mainly the epidemiological</p> <p>10 literature, that is true. Again, but I'm not</p> <p>11 doing causation, so I didn't approach it that</p> <p>12 way.</p> <p>13 But certainly if you look at</p> <p>14 what I did, it's consistent with that because</p> <p>15 I talk about the differences between the</p> <p>16 limitations of a case-control versus a</p> <p>17 prospective study. I talk about both the</p> <p>18 positives and the negatives within the</p> <p>19 database, but I don't lay it out in a table</p> <p>20 like they do. But it's certainly the same</p> <p>21 basic process.</p> <p>22 I was actually quite surprised</p> <p>23 at how similar the database of information</p> <p>24 that they reviewed was to what I honed in on</p> <p>25 as well.</p> | <p>1 I know I'm going to write, such as exposure</p> <p>2 migration, and then I -- as I'm reading a</p> <p>3 paper, I'll type in a paper -- the ones that</p> <p>4 I believe are important to my overall</p> <p>5 assessment. So I will do that as I'm -- as</p> <p>6 I'm going through the evidence.</p> <p>7 So that's one of the tools I</p> <p>8 use, but I don't keep notes. I just kind of</p> <p>9 use that as a living document that eventually</p> <p>10 becomes a report.</p> <p>11 Q. Do your opinions ever change as</p> <p>12 you read additional pieces of scientific</p> <p>13 evidence?</p> <p>14 A. Yes, it does. It may change.</p> <p>15 And it often -- often the changes, though,</p> <p>16 are not that I believe -- with the exception</p> <p>17 of epidemiology. In other areas.</p> <p>18 Epidemiology is a little bit different issue</p> <p>19 when you're reviewing studies.</p> <p>20 But on toxicology I always</p> <p>21 start with reviews and regulatory</p> <p>22 authorities, looking at what others have said</p> <p>23 generally about the toxicology. And so even</p> <p>24 though I may refine opinions differently or I</p> <p>25 might change, I certainly wouldn't agree to</p> |

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| <p>1 work on a project to start with if my initial</p> <p>2 reviews on hazard, for example, didn't</p> <p>3 convince me that I believe that there is a</p> <p>4 hazard. But you refine it from there.</p> <p>5 That's exactly right.</p> <p>6 So there are cases, however,</p> <p>7 where I'm asked to work on a project where</p> <p>8 there is no review or regulatory authority or</p> <p>9 any kind of assessment over a period of</p> <p>10 years, and in those cases there are times</p> <p>11 when I start working on a project and I stop</p> <p>12 and say, "I can't do this." Because that</p> <p>13 happens, yes.</p> <p>14 So opinions do change sometimes</p> <p>15 based on review of additional information.</p> <p>16 Q. Is there any documentation that</p> <p>17 you've produced either in your report or</p> <p>18 otherwise in the MDL that would allow someone</p> <p>19 reviewing the material to understand the</p> <p>20 order in which you reviewed materials or the</p> <p>21 specific weight that you assign them?</p> <p>22 A. So order of review, no. I</p> <p>23 don't think you would know that other than --</p> <p>24 you will note order of review if you look at</p> <p>25 the differences in the literature cited in my</p> | <p>1 your report that have been criticized by</p> <p>2 others at some point in time, correct?</p> <p>3 A. Yes, that's true.</p> <p>4 Q. Okay. Now, in some instances</p> <p>5 you state that you then give little weight to</p> <p>6 those studies, correct?</p> <p>7 A. Yes.</p> <p>8 Q. But in other instances you find</p> <p>9 the criticized study to be helpful and</p> <p>10 informative, correct?</p> <p>11 A. That's true. Because, again,</p> <p>12 judgment -- as anybody does weight of the</p> <p>13 evidence, different scientists can have</p> <p>14 different judgment.</p> <p>15 Mainly, I think, when I look at</p> <p>16 the differences in that -- in that regard, I</p> <p>17 think you should pay attention to what the</p> <p>18 person is. So as a toxicologist, I may view</p> <p>19 a certain type of -- piece of data very</p> <p>20 differently than an epidemiologist may view</p> <p>21 it, as far as the reliability or the</p> <p>22 relevance, because we're coming at it from a</p> <p>23 different training and experience and</p> <p>24 judgment -- set of judgment on what is</p> <p>25 important to a toxicologist when I'm talking</p> |
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| <p>1 original report versus in the MDL.</p> <p>2 So in my original reliance</p> <p>3 list, if there were documents that weren't</p> <p>4 there and they're now here, obviously that</p> <p>5 tells you it was a review.</p> <p>6 On the issue of a -- of the</p> <p>7 weight of the evidence process, the only</p> <p>8 answer I can give you for that is that</p> <p>9 articles that I believe are -- are reliable,</p> <p>10 are relevant and are -- those are kind of</p> <p>11 the -- you look at the reliability of the</p> <p>12 studies, whether they're peer-reviewed or not</p> <p>13 or if they have proper controls put into</p> <p>14 place, things like that, whether or not</p> <p>15 the -- they're relevant to the question at</p> <p>16 hand. That you can get from looking at how I</p> <p>17 discuss them in the document. But certainly</p> <p>18 there's no, like, summary of that.</p> <p>19 But certainly -- I think you</p> <p>20 understand -- you should understand when you</p> <p>21 read my report what weight I'm giving based</p> <p>22 on how I'm describing those -- those</p> <p>23 materials. I mean, it's --</p> <p>24 Q. Well, for example, you do have</p> <p>25 different studies that you've identified in</p> | <p>1 about risk versus how an epidemiologist might</p> <p>2 talk about risk.</p> <p>3 Q. Could two different</p> <p>4 toxicologists review the same piece of</p> <p>5 literature and give it very different weight?</p> <p>6 A. I don't know about different</p> <p>7 weight, but they certainly -- I know people</p> <p>8 come to different conclusions based on their</p> <p>9 overall assessments. That happens,</p> <p>10 definitely. I mean, there are always going</p> <p>11 to be individuals that look at things</p> <p>12 differently.</p> <p>13 I know in this case there are</p> <p>14 people -- I've seen defense experts that</p> <p>15 reports in -- not in the MDL but in other</p> <p>16 cases, where people disagree with some of my</p> <p>17 opinions, and I disagree with their opinions.</p> <p>18 That happens.</p> <p>19 Q. Okay. And so if I were --</p> <p>20 well, let me just ask something. You have</p> <p>21 not provided any sort of quantitative</p> <p>22 assessment of the weight that you gave</p> <p>23 different pieces of evidence that you cite in</p> <p>24 forming your opinions in the MDL, correct?</p> <p>25 MS. PARFITT: Objection.</p> |

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| <p>1 Misstates her testimony.</p> <p>2 MR. MEADOWS: Objection.</p> <p>3 THE WITNESS: So I don't report</p> <p>4 for you a table where I quantify that,</p> <p>5 that is correct, but certainly that</p> <p>6 is -- because, again, based upon</p> <p>7 looking at the way that I was trained</p> <p>8 and the documents that I'm talking --</p> <p>9 I'm pointing you to to describe how to</p> <p>10 do weight of the evidence, it is</p> <p>11 not -- it is not a numerical exercise,</p> <p>12 how many here, how many there, this</p> <p>13 one gets 5 points because of this or</p> <p>14 6 points because of this.</p> <p>15 It's more an issue, again, of</p> <p>16 judgment. It's the idea of looking</p> <p>17 across all of the available</p> <p>18 information and determining whether or</p> <p>19 not, based on that, it's your opinion</p> <p>20 that there -- that, for example,</p> <p>21 talc -- talc's toxicity profile</p> <p>22 includes cancer. That's one of the</p> <p>23 judgments -- weight of the evidence</p> <p>24 judgments you make, for example.</p> <p>25</p> | <p>1 you're looking at.</p> <p>2 The robustness of the data.</p> <p>3 For example, the NTP GLP quality</p> <p>4 animal study, very high quality in the</p> <p>5 weight of the evidence. And I talked</p> <p>6 to you about that. In fact, it --</p> <p>7 even though people criticize that</p> <p>8 study, that study is very valuable for</p> <p>9 looking at biologic changes that are</p> <p>10 consistent with a carcinogenic</p> <p>11 mechanism being initiated.</p> <p>12 So even though you may say that</p> <p>13 you can't quantify risk from that</p> <p>14 animal study as far as calculating a</p> <p>15 cancer potency factor, what you can do</p> <p>16 is use that study of high quality to</p> <p>17 make judgments within a weight of the</p> <p>18 evidence for risk.</p> <p>19 QUESTIONS BY MS. BRANSCOME:</p> <p>20 Q. Dr. Plunkett, you understand I</p> <p>21 have seven hours today, and I -- while I'm</p> <p>22 very interested in the answers that you give,</p> <p>23 if we could just -- we will get to things</p> <p>24 like NTP when we get there, if you could just</p> <p>25 attempt to answer the question that I've</p> |
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| <p>1 QUESTIONS BY MS. BRANSCOME:</p> <p>2 Q. So -- but, Dr. Plunkett, just</p> <p>3 to be clear, you do not provide a numerical</p> <p>4 value to the particular pieces of evidence</p> <p>5 that you have considered as part of your</p> <p>6 weight of the evidence assessment in the MDL,</p> <p>7 correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: So I do not</p> <p>10 provide a numerical value as you see</p> <p>11 it laid out, for example, in the</p> <p>12 Canadian table, but certainly I do</p> <p>13 judge articles that I include in my</p> <p>14 weight of the evidence based on a</p> <p>15 system that includes different</p> <p>16 considerations such as -- like I said,</p> <p>17 peer-reviewed or not, that makes an</p> <p>18 issue.</p> <p>19 Whether or not the study that's</p> <p>20 being reported is the only one -- the</p> <p>21 first or is this something that is --</p> <p>22 that is describing an assessment</p> <p>23 that's been done by someone else and</p> <p>24 so you see a repetition or a</p> <p>25 consistency among the studies that</p> | <p>1 asked.</p> <p>2 I simply asked the question:</p> <p>3 Are there numerical values assigned to the</p> <p>4 particular pieces of evidence that you have</p> <p>5 considered as part of your weight of the</p> <p>6 evidence assessment in reaching your opinions</p> <p>7 in the MDL; yes or no?</p> <p>8 A. And I said to you, not in the</p> <p>9 way that it's done -- I assume you're</p> <p>10 referring to something like what was done --</p> <p>11 what's in the Canadian epidemiology table. I</p> <p>12 have not done that, no.</p> <p>13 Q. Okay.</p> <p>14 A. That's exactly right.</p> <p>15 Q. Have you provided a qualitative</p> <p>16 chart, for example, of the evidence that you</p> <p>17 have considered in forming your opinions in</p> <p>18 the MDL?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 THE WITNESS: I don't know what</p> <p>21 you mean by qualitative chart. I</p> <p>22 certainly have -- I certainly, I</p> <p>23 believe, have given you qualitative</p> <p>24 descriptions of my weight within my</p> <p>25 discussions of each study, yes, I have</p> |

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| <p>1 done that.</p> <p>2 QUESTIONS BY MS. BRANSCOME:</p> <p>3 Q. You mention in response to the</p> <p>4 prior question that you have a system for</p> <p>5 weighting the pieces of evidence that you</p> <p>6 have reviewed.</p> <p>7 Can you point me to paragraphs</p> <p>8 in your report marked Exhibit 4 that would</p> <p>9 outline in detail the system that you used to</p> <p>10 apply different weight analysis to different</p> <p>11 pieces of evidence?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: And I think I</p> <p>14 answered that, that there's no system</p> <p>15 written down by anyone. But what</p> <p>16 there is, instead, is if you read</p> <p>17 these -- if you read these</p> <p>18 descriptions of use of weight of the</p> <p>19 evidence that I've cited in</p> <p>20 paragraph 13 as well as the discussion</p> <p>21 of methodology in the Canadian</p> <p>22 document, that is consistent with what</p> <p>23 I do. It's the idea that you start</p> <p>24 with a literature search for</p> <p>25 peer-reviewed, publicly available</p> | <p>1 published afterwards, and what I</p> <p>2 thought I said to you was that if you</p> <p>3 look at that document -- it's not in</p> <p>4 paragraph 13, but if you look at that</p> <p>5 document, it lays out a process. And</p> <p>6 I wouldn't call it a system. It's a</p> <p>7 process. It's a process by which you</p> <p>8 screen information for relevance to</p> <p>9 the question being asked and how,</p> <p>10 then, based on that, you look at</p> <p>11 characteristics of that information</p> <p>12 such as -- and I tried to give you</p> <p>13 some of those.</p> <p>14 And I've said this before in</p> <p>15 depositions in these cases. You know,</p> <p>16 you look at the issue of whether or</p> <p>17 not the study was peer-reviewed,</p> <p>18 whether or not there was</p> <p>19 statistically -- statistical</p> <p>20 significance or at least statistics</p> <p>21 applied to the data. What was the</p> <p>22 quality of the study as far as the</p> <p>23 size in order to be able to answer the</p> <p>24 question being asked. Those are the</p> <p>25 kinds of things that you look at.</p> |
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| <p>1 information. You look at the quality</p> <p>2 of the studies, the statistically</p> <p>3 significant findings. Those are all</p> <p>4 things that are discussed within these</p> <p>5 documents I'm pointing you to.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Now, you --</p> <p>8 A. But it's -- it's -- I don't</p> <p>9 know of anyone who has written down a</p> <p>10 specific system that applies in all</p> <p>11 circumstances, no.</p> <p>12 Q. Okay. Have you written down a</p> <p>13 system that applies specifically in this</p> <p>14 case?</p> <p>15 A. I think I have tried to do that</p> <p>16 for you when I describe what I did.</p> <p>17 Q. Okay. You just referenced the</p> <p>18 fact that your system can be found in the</p> <p>19 Canadian document.</p> <p>20 You agree that the Canadian</p> <p>21 analysis was actually published or produced</p> <p>22 after you had completed your report in the</p> <p>23 MDL, correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: Certainly it was</p> | <p>1 And then also the question --</p> <p>2 when you're looking at a specific</p> <p>3 question, you may pull in -- like you</p> <p>4 asked me about the starch particle.</p> <p>5 You may pull in things that you give</p> <p>6 less weight because obviously that's</p> <p>7 not just talc, that's starch, and you</p> <p>8 have to consider that. So that is</p> <p>9 part of the process.</p> <p>10 QUESTIONS BY MS. BRANSCOME:</p> <p>11 Q. Dr. Plunkett, the question I</p> <p>12 asked you simply was: The paper that you</p> <p>13 reference that contains some detail about the</p> <p>14 Canadian analysis, that was published after</p> <p>15 you completed your report that's marked here</p> <p>16 as Exhibit 4; is that correct?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: Yes, and I</p> <p>19 believe I answered that at the start.</p> <p>20 I usually try to answer your question,</p> <p>21 and then I try to explain further some</p> <p>22 details I think are important context</p> <p>23 on my answer.</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. I understand that,</p> |

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| <p>1 Dr. Plunkett. You have given many 2 depositions. You understand I can ask you 3 for more detail if that would be helpful to 4 me. 5 If you could, just focus on the 6 question that I asked, and we can explore 7 additional areas if that's something I'm 8 interested in doing. 9 Okay? 10 MR. MEADOWS: Objection. 11 She's -- 12 MS. BOCKUS: Break? 13 MR. MEADOWS: After I finish my 14 objection. 15 She's going to answer the 16 question as thoroughly as she feels 17 like she needs to answer the question 18 based on the way you ask it. 19 Want to take a break now? 20 MS. BRANSCOME: We can go off 21 the record. 22 VIDEOGRAPHER: We're going off 23 the record at 10:41 a.m. 24 (Off the record at 10:41 a.m.) 25 VIDEOGRAPHER: We are back on</p> | <p>1 panel; is that correct? 2 A. Yes. 3 Q. And so is it your view that a 4 study or an analysis that reaches a 5 particular conclusion should be assigned 6 little weight if it fails to consider all 7 relevant scientific evidence to the issue 8 that it's evaluating? 9 MS. PARFITT: Objection. 10 THE WITNESS: I think it 11 depends on the situation, but that 12 could be the case, yes. It depends 13 on -- on the -- depends on -- I think 14 it would depend on each case, the 15 question being asked, and what was 16 omitted. But, yes, I think it could. 17 QUESTIONS BY MS. BRANSCOME: 18 Q. Okay. And in this situation 19 you identify -- I believe you claimed that 20 eight human studies were not considered by 21 the CIR 2013 panel; is that correct? 22 A. Let me look at the number, but 23 that sounds about right. Yes. 24 Q. All right. And returning, 25 actually, to your prior answer, you said that</p> |
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| <p>1 the record at 10:56 a.m. 2 QUESTIONS BY MS. BRANSCOME: 3 Q. All right. Dr. Plunkett, we 4 started talking a little bit about the CIR 5 analysis that was done in 2013. 6 Am I correct you no longer 7 consider that reliable? Is that your 8 opinion? 9 A. Yes. 10 Q. Okay. And you identify in your 11 report marked as Exhibit 4, I believe it's 12 paragraph 56? 13 A. Yes, that's correct. And I 14 think I talked about it later on as well, but 15 definitely I do here. 16 Q. Okay. And in paragraph 56, you 17 state that the CIR panel failed to account 18 for all the studies that informed on the 19 issue of migration of particles such as talc 20 upwards through the reproductive tract. 21 Is that your opinion? 22 A. Yes. 23 Q. Okay. And then you state that 24 because of that you assign, quote, little 25 weight to the conclusions reached by the CIR</p> | <p>1 the failure to consider all relevant 2 scientific evidence on a topic would lead you 3 to assign little weight to a particular 4 conclusion. You said that that could happen. 5 Under what circumstances would 6 you assign a conclusion little weight for 7 failing to consider what you consider to be 8 all relevant pieces of scientific literature? 9 A. Well, I think it depends -- 10 well, the reason I specifically addressed 11 that in this case is because that was -- the 12 conclusions about migration is the main 13 reason why the CIR panel then draws 14 additional conclusions later on. 15 So my issue is, migration was 16 key to what -- the decisions they made about 17 the safety issues of talc. And so in that 18 particular case, this -- this failure to 19 consider all the evidence was extremely 20 important, in my view, and I gave it little 21 weight. 22 There might be a situation 23 where some -- for example, you may only look 24 at six or eight studies, even though there 25 may be dozens out there. You may have a</p> |

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| <p>1 reason for why you only looked at six or 2 eight, or it may be -- and as a result you 3 may lay that out and, therefore, you may 4 still give weight to conclusions drawn. Or 5 it may be that the six or eight are -- 6 studies that you discuss are not -- the 7 weight is not affected by what you've 8 omitted.</p> <p>9 I believe that the weight is 10 affected by what is omitted when you look at 11 some of the articles being review articles, 12 which give you an understanding of what was 13 generally accepted within the scientific 14 community when you get to reviews, those 15 kinds of things. So it really is a 16 case-by-case basis.</p> <p>17 But certainly I do believe that 18 it is possible that in another circumstance 19 where things are omitted you would come to 20 the same conclusion, that you give those 21 conclusions less weight.</p> <p>22 Q. Is there a way, if someone were 23 try to replicate the weighting of particular 24 evidence based upon your process, for them to 25 know whether or not the omission of a</p> | <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. Of the eight studies 3 that you identify on page 37 of your report 4 that you contend the CIR panel did not 5 account for, do any of those eight studies 6 specifically discuss the migration of talc in 7 human subjects? 8 A. No, I don't believe they do, 9 but there are a couple of these studies that 10 I found to be extremely important if you want 11 me to explain that to you. 12 Q. Do you break out in your report 13 in any other paragraphs which of these eight 14 articles you consider to be extremely 15 important? 16 And if you could just point me 17 to paragraph numbers, that's good enough if 18 you have, in fact, broken them out. 19 A. I have. I -- this whole 20 section I break -- I talk about each one 21 individually. So I think you can tell by 22 what I read -- what I'm discussing what I 23 thought was important and informative about 24 each of those. 25 Q. Do you rank the eight studies</p> |
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| <p>1 citation of certain studies means that a 2 study should be given little weight or 3 whether it wouldn't affect the weighting of 4 that scientific article?</p> <p>5 MS. PARFITT: Objection. Form. 6 THE WITNESS: So I think this 7 is the issue of judgment, training and 8 experiencing that is applied to all 9 such assessments, and this is why 10 different scientists may come to 11 different conclusions. But certainly 12 it is -- it was important to my 13 assessment on this issue because of 14 the prominent role that the CIR report 15 gives to their conclusions here for 16 why they then drew conclusions about 17 safety. And so that link was 18 extremely important.</p> <p>19 MS. BRANSCOME: Can we pause 20 for just a moment? 21 VIDEOGRAPHER: We are going off 22 the record at 11:00 a.m. 23 (Off the record at 11:00 a.m.) 24 VIDEOGRAPHER: We are back on 25 the record at 11:01 a.m.</p> | <p>1 in any way by their importance to you? 2 A. Not with any numerical rank, 3 no, but certainly I think I do that for you 4 when I talk about the studies. I give you an 5 understanding of ones that I think are 6 particularly informative and ones that are 7 not.</p> <p>8 So, for example, I weight the 9 human data -- I think I tell you that -- more 10 than the animal data because of the 11 differences between the reproductive tracts 12 of humans versus animals generally, upright 13 versus -- upright and habits and things that 14 humans do that relate to insertions in and 15 out of the reproductive tract, I guess is a 16 nice way to describe it, versus an animal, 17 that those can have, and then also the 18 differences between animals and humans in 19 terms of bursal sac around the ovary, those 20 kinds of things.</p> <p>21 So I do -- that -- I guess that 22 ranking I do give you here. I tell you that 23 I think these -- I think that the most 24 relevant are going to be the human studies 25 versus the animal studies.</p> |

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| <p>1 Q. Right.</p> <p>2 So my question specifically is,</p> <p>3 where would you point me to in your report to</p> <p>4 understand the weight that you gave each of</p> <p>5 these particular eight studies?</p> <p>6 A. At my descriptions of those</p> <p>7 studies and what I describe. That's all I</p> <p>8 can tell you.</p> <p>9 Q. And I'm just asking,</p> <p>10 Dr. Plunkett, can you point me in the report</p> <p>11 to where that discussion takes place?</p> <p>12 A. It takes place -- I have a</p> <p>13 discussion for each study, and I would -- and</p> <p>14 if you read what I say about each study, I</p> <p>15 try to go through what the strengths and</p> <p>16 weaknesses of those studies are.</p> <p>17 And so those -- that would be,</p> <p>18 let's see -- you want me to give you the</p> <p>19 starting paragraph?</p> <p>20 Q. So, for example, Parmley and</p> <p>21 Woodruff. Can you point me to where in your</p> <p>22 report you discuss Parmley and Woodruff, such</p> <p>23 that I can understand the weight that you</p> <p>24 gave that particular study?</p> <p>25 A. So the year of it is...</p> | <p>1 So what I do is, when I'm</p> <p>2 discussing about these -- all of these papers</p> <p>3 here contribute to my weight of the evidence.</p> <p>4 And if it's a human study, I'm giving those</p> <p>5 more weight than I'm giving animal studies.</p> <p>6 And that's described.</p> <p>7 And then within papers I'm</p> <p>8 pulling out information that contributes to</p> <p>9 what I think is important about what the</p> <p>10 study says, and that -- and the importance of</p> <p>11 what is described within the study</p> <p>12 contributes to my weight.</p> <p>13 And I don't know how else to</p> <p>14 describe it to you. That is the process that</p> <p>15 scientists go through when they evaluate</p> <p>16 data.</p> <p>17 Q. And so my question to you:</p> <p>18 Earlier you said of these eight studies, some</p> <p>19 of them were particularly important to you.</p> <p>20 How would I, using only what's</p> <p>21 written in your report, understand which of</p> <p>22 those eight studies was of particular</p> <p>23 importance to you?</p> <p>24 A. So it would have to do with</p> <p>25 what I discuss about the study. So I'm</p> |
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| <p>1 So I think I discuss it in</p> <p>2 paragraph 44, and so I describe for you what</p> <p>3 important information is in there, which is</p> <p>4 the information that I take as forming part</p> <p>5 of my weight of the evidence.</p> <p>6 So one of the most important</p> <p>7 things is what -- they have a figure they</p> <p>8 show, and they're showing -- which is one of</p> <p>9 the unique figures in all of the published</p> <p>10 literature. But it talks about the</p> <p>11 differences between the female reproductive</p> <p>12 tract and the male reproductive tract, and it</p> <p>13 shows the actual -- it talks about a</p> <p>14 discussion of movement from substance in the</p> <p>15 environment through -- into the vagina, into</p> <p>16 the fallopian tubes. So it's a paper that</p> <p>17 addresses that very specific issue.</p> <p>18 Q. So my question to you, though,</p> <p>19 is, where do you have a discussion of the</p> <p>20 weight that you give to these particular</p> <p>21 articles?</p> <p>22 A. So the discussion of the weight</p> <p>23 has to do with the information described. I</p> <p>24 don't give them a numerical ranking. I told</p> <p>25 you that.</p> | <p>1 telling you, when I -- if you look through</p> <p>2 this entire section, this is the Parmley and</p> <p>3 Woodruff paper. It is important because it</p> <p>4 addresses the specific issue of movement of</p> <p>5 environmental substances from the outside to</p> <p>6 the inside. So I'm giving that importance in</p> <p>7 my evaluation because of what that author is</p> <p>8 actually discussing.</p> <p>9 I don't know how else to</p> <p>10 describe that. I apologize. I mean, to me,</p> <p>11 weight of the evidence is a process that</p> <p>12 scientists use bringing their training and</p> <p>13 experience and judgment, and it's not a</p> <p>14 numerical process across the board, it just</p> <p>15 is not, based on the way weight of the</p> <p>16 evidence is used within science.</p> <p>17 Q. Now, Dr. Plunkett, though, you</p> <p>18 would acknowledge that if you wanted to</p> <p>19 assign numerical values to the studies, that</p> <p>20 has been something that has been done by</p> <p>21 other authors and other authors on whom you</p> <p>22 rely, correct?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: I don't believe</p> <p>25 that's true. I'll need to look -- I</p> |

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| <p>1 don't believe that's true with respect 2 to the biological information. I 3 believe it may be true with respect to 4 the epidemiology studies. 5 You want me to look real quick 6 to confirm that? I can do that really 7 quick, but... 8 QUESTIONS BY MS. BRANSCOME: 9 Q. I'm simply saying, could you 10 assign a numerical value if you chose to do 11 so? 12 MR. MEADOWS: Objection. 13 Objection. Form. 14 THE WITNESS: And I'm -- what 15 I'm trying to say to you is I think 16 that I -- that there is no one set of 17 rules that you would assign in order 18 to do that for all the types of 19 studies that you weigh. 20 I would agree that I have seen 21 it routinely done -- well, not 22 routinely, but I've seen it done 23 within the epidemiological community 24 when they go through the epi data. 25 But not -- it's not something that</p> | <p>1 Q. All right. And you are aware 2 that there is, in fact -- called PDQs, 3 correct? 4 A. That's the abbreviation, yes. 5 Q. Right. And you're aware that 6 the National Cancer Institute has in fact 7 published a PDQ that addresses a potential 8 connection between talc and ovarian cancer, 9 correct? 10 A. I'm aware of several that have 11 been done over the years, but, yes, I'm aware 12 of that. 13 Q. And have you reviewed those? 14 A. Yes, I have. 15 Q. Are they listed on your 16 reliance list? 17 A. No, but they're listed within 18 the materials as discussed within my 19 depositions, and I thought -- and my 20 testimony. I thought that was part of my 21 reliance list. I believe that it -- it was 22 in my reliance list, is encompassing all of 23 the testimony as well as the actual 24 documents. Maybe I'm mistaken, but that was 25 my understanding.</p> |
| Page 107 | Page 109 |
| <p>1 I've seen done when you talk about 2 weight of the evidence as part of a 3 human health risk assessment. That is 4 not something that scientists 5 typically do as far as giving 6 numerical rankings. 7 QUESTIONS BY MS. BRANSCOME: 8 Q. You're familiar with the 9 National Cancer Institute, correct? 10 A. Yes, I am. 11 Q. All right. They are considered 12 to be the nation's leader in cancer research, 13 correct? 14 MS. PARFITT: Objection to 15 form. 16 THE WITNESS: The National 17 Cancer Institute? 18 Yes, they are. I don't know if 19 they're "the" leading, but they're one 20 of the leading, that's true. 21 QUESTIONS BY MS. BRANSCOME: 22 Q. Okay. And you're familiar with 23 publications that they issue called physician 24 data queries? 25 A. Yes, I am.</p> | <p>1 Q. Okay. If they are not on your 2 reliance list, should they be? 3 A. I believe that they are on my 4 reliance list by it having been pointed to as 5 part of the testimony that I have given and 6 the documents that I have relied upon during 7 testimony. 8 Q. Okay. And you are aware that 9 they have issued a PDQ that -- on the website 10 as of today, correct? 11 A. I haven't looked today, so I'm 12 sure -- but I know that -- I don't believe it 13 has been removed, so I believe that there is 14 something there, yes. 15 Q. All right. And what is your 16 understanding of the position stated in the 17 PDQ with respect to a possible link between 18 talc and ovarian cancer? 19 A. So I'd have to look at the one 20 today to tell you what it says, but it's 21 evolved over time and it's changed over time, 22 and I have specific opinions that I've 23 expressed at trial about that issue. 24 Do you want me to go into that 25 details or I mean --</p> |

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| <p>1 Q. I'm not asking about your 2 opinions about what their position is. I'm 3 simply asking you, Dr. Plunkett, the most 4 recent NCI PDQ that you have reviewed, what 5 is the position that the National Cancer 6 Institute has taken with respect to the 7 relationship between talc and ovarian cancer? 8 A. So I would want to pull it out 9 to give you the specific statement of their 10 position, but their position has changed such 11 that later in time they've weakened the 12 link -- their statements about the link 13 between ovarian cancer and genital talc use. 14 So it used to be seen as a 15 cause, and now I believe it's not seen as a 16 cause. I don't know the exact language, 17 though. I'd have to look at it as -- maybe 18 risk factor is the better word to use. 19 And I need to look at the most 20 recent one. And that would be the best way. 21 Let's just see what it says. 22 Q. Okay. 'Cause is it your 23 position as you sit here today that the 24 National Cancer Institute has ever issued a 25 statement that talc causes ovarian cancer?</p> | <p>1 any -- whatever portion of this is helpful to 2 you. 3 And then if you could answer my 4 question, Dr. Plunkett, of what is the 5 position as stated in Deposition Exhibit 6 Number 7 of the National Cancer Institute 7 with respect to the relationship between talc 8 and ovarian cancer? 9 A. So I would be looking at the 10 section on page 12 of 18, and maybe you're 11 looking somewhere else, but that's where they 12 actually talk about perineal talc exposure. 13 And it's under the section where they have 14 now moved into factors with an adequate 15 evidence of an association and they describe 16 it here. So they're calling it an 17 association where the weight of the evidence 18 is not adequate to support that association. 19 Q. All right. And so the first 20 sentence of the section under perineal talc 21 exposure states, "The weight of the evidence 22 does not support an association between 23 perineal talc exposure and an increased risk 24 of ovarian cancer." 25 Did I read that correctly?</p> |
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| <p>1 A. I believe it was listed as a 2 risk factor for ovarian cancer in the older 3 PDQs. 4 (Plunkett Exhibit 7 marked for 5 identification.) 6 QUESTIONS BY MS. BRANSCOME: 7 Q. I do have a copy here. Just 8 for the sake of the record, we will mark this 9 as Plunkett Deposition Exhibit Number 7. 10 Handing a copy to you, 11 Dr. Plunkett, do you recognize the document 12 that I just handed you that's marked as 13 Exhibit 7? 14 MR. LOCKE: What's the date of 15 that? 16 MS. BRANSCOME: This was 17 printed on December 14, 2018. 18 THE WITNESS: It's -- the 19 updated date is June 22, 2018, if that 20 helps. 21 MR. LOCKE: Yes, thank you. 22 THE WITNESS: I have seen this 23 one, yes. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. All right. And you can review</p> | <p>1 A. You did read that correctly. 2 Q. All right. And it indicates 3 that "results from case-control and cohort 4 studies are inconsistent." 5 Did I read that correctly, 6 Dr. Plunkett? 7 A. You did. 8 Q. And the question that I would 9 ask simply is, do you discuss the National 10 Cancer Institute PDQ in the report that 11 you've issued in the MDL, which is identified 12 as Exhibit 4? 13 A. I don't specifically discuss 14 this document, no, I do not. 15 Q. Okay. And you understand that 16 the NCI PDQ did a weight of the evidence 17 analysis that followed a formal evidence 18 ranking system, correct? 19 MS. PARFITT: Objection. 20 THE WITNESS: So I -- it's not 21 laid out here, but they do have a 22 process they use. 23 Is that what you're asking me? 24 QUESTIONS BY MS. BRANSCOME: 25 Q. Yes.</p> |

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| <p>1 A. Yes. And again, they're</p> <p>2 ranking the epidemiological data, and so I</p> <p>3 understand that that is there, yes.</p> <p>4 Q. Now, you've said a few times</p> <p>5 that you could qualitative -- you could give</p> <p>6 a quantitative weight to an epidemiological</p> <p>7 study, somehow suggesting that it is</p> <p>8 different from other types of studies.</p> <p>9 What is it about a</p> <p>10 toxicological study, for example, that would</p> <p>11 prevent someone from giving a quantitative</p> <p>12 weight in a weight of the evidence analysis?</p> <p>13 A. Because it is just what is</p> <p>14 typically done and not done. There are</p> <p>15 certain practices within the community, what</p> <p>16 is kind of -- I would say that scientists use</p> <p>17 routinely, or scientists have used. Not all</p> <p>18 scientists give numerical rankings to</p> <p>19 epidemiological data either, because even</p> <p>20 within a Bradford Hill assessment, when you</p> <p>21 use the considerations, there's no</p> <p>22 requirement for ranking studies in order to</p> <p>23 meet the requirements of use of that</p> <p>24 methodology.</p> <p>25 Q. Okay.</p> | <p>1 of epidemiological evidence?</p> <p>2 A. If by -- you mean prevent, was</p> <p>3 someone stopping me from doing that, no. But</p> <p>4 if you ask what would be standard practice</p> <p>5 based on my experience, I would not be doing</p> <p>6 that.</p> <p>7 Q. Has anyone -- and I'm not</p> <p>8 referring in this case to any attorneys. But</p> <p>9 has anyone reviewed your -- the weighting</p> <p>10 that you gave specific pieces of evidence as</p> <p>11 essentially a form of a peer review process?</p> <p>12 A. If by that you mean have I</p> <p>13 submitted my opinions for publication, no, I</p> <p>14 have not done that. Part of -- that's partly</p> <p>15 driven by my understanding of the evidence</p> <p>16 that I reviewed, that some of it may not be</p> <p>17 something that I should be discussing</p> <p>18 necessarily in a public form outside of the</p> <p>19 cases I'm working in.</p> <p>20 But certainly I have not</p> <p>21 submitted it for publication, if that's what</p> <p>22 you mean. No, I have not done that.</p> <p>23 Q. Okay. Has the methodology that</p> <p>24 you have used in the MDL, has that been --</p> <p>25 have you submitted any type of analysis using</p> |
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| <p>1 A. But I have seen it done in the</p> <p>2 epidemiology community, and that is the most</p> <p>3 common place I see it. I do not see other</p> <p>4 toxicologists that are assessing animal</p> <p>5 studies and in vitro studies doing it that</p> <p>6 same way.</p> <p>7 When you do a human health risk</p> <p>8 assessment, that isn't routine practice to do</p> <p>9 numerical rankings on studies.</p> <p>10 Q. Okay.</p> <p>11 A. At least in my experience and</p> <p>12 in my training, and I was trained in the use</p> <p>13 of risk assessment by one of the individuals</p> <p>14 who actually invented the process.</p> <p>15 Q. Okay. Okay. But do you</p> <p>16 consider the epidemiological evidence as part</p> <p>17 of your risk assessment in the MDL?</p> <p>18 A. I do, because I'm looking at it</p> <p>19 in the context of what is out there and</p> <p>20 what's available. I don't always have human</p> <p>21 data when I do risk assessments, but in this</p> <p>22 one I do. So I do consider them, yes.</p> <p>23 Q. Okay. Did anything prevent you</p> <p>24 from doing a quantitative assessment of the</p> <p>25 weight that you were giving different pieces</p> | <p>1 that methodology for publication even outside</p> <p>2 of particularly looking at Johnson's baby</p> <p>3 powder, for example?</p> <p>4 A. Yes, in -- if you look at my</p> <p>5 publications that describe risk assessments</p> <p>6 that I have done. So the one that would come</p> <p>7 to -- to play that's similar as far as the</p> <p>8 scope of the weight of the evidence would --</p> <p>9 at least with the animal and the in vitro</p> <p>10 studies, would be the paper that I published</p> <p>11 on copper, looking at the database of copper</p> <p>12 and identifying points of departure and</p> <p>13 target organs and risk -- risk issues based</p> <p>14 on copper use in humans, trying to set a --</p> <p>15 understand what a safe exposure level could</p> <p>16 be to copper in water. And that was</p> <p>17 published -- that actually was one of the</p> <p>18 papers that's published with Dr. Krewski, who</p> <p>19 is one of the authors of this risk assessment</p> <p>20 in Canada.</p> <p>21 Q. And is it your position that</p> <p>22 you follow the same methodology in what</p> <p>23 you've reported in the MDL with respect to</p> <p>24 Johnson's baby powder that you did in your</p> <p>25 analysis of copper?</p> |

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| <p>1 A. Yes, with the process of going</p> <p>2 through all of the publicly available</p> <p>3 information, putting it together based on its</p> <p>4 relevancy and reliability.</p> <p>5 We did a process where we</p> <p>6 grouped it based on animal versus human, just</p> <p>7 like I've done here. And we call it the</p> <p>8 bins, but it's the same idea. I have a bin</p> <p>9 of human data, I have a bin of animal data</p> <p>10 and a bin of in vitro data. And so, yes, the</p> <p>11 process was very, very similar.</p> <p>12 Q. Okay. Returning back to some</p> <p>13 documents that you chose not to cite in your</p> <p>14 report, you do not discuss the Gonzales 2016</p> <p>15 study in your report for the MDL, correct?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 THE WITNESS: I'll have to</p> <p>18 look. It is not cited in the</p> <p>19 reference list to my report, that is</p> <p>20 true. So that means it would not be</p> <p>21 mentioned specifically in the body of</p> <p>22 the report.</p> <p>23 QUESTIONS BY MS. BRANSCOME:</p> <p>24 Q. You're familiar with the</p> <p>25 Gonzalez 2016 study, correct?</p> | <p>1 include something like the Gonzales 2016</p> <p>2 study, but yet you will disagree the</p> <p>3 2013 -- the CIR 2013, you will give it little</p> <p>4 weight for not discussing particular studies?</p> <p>5 A. So that's a very different</p> <p>6 exercise. You want me to explain my thinking</p> <p>7 on that? I can do that for you, but I</p> <p>8 believe that's apples and oranges question.</p> <p>9 My reasons for giving little</p> <p>10 weight to the CIR overall assessment versus</p> <p>11 my weight or the assessment I make of an</p> <p>12 individual piece of data, that's different.</p> <p>13 And that's what you're describing for me.</p> <p>14 And I believe Gonzales is in my</p> <p>15 overall reliance list, so I have read</p> <p>16 Gonzales. It is something that I have</p> <p>17 considered; it's not something that I've</p> <p>18 cited in my paragraphs. So it doesn't mean</p> <p>19 it didn't go into my weight of the evidence,</p> <p>20 because I do have it and I have reviewed it.</p> <p>21 I just don't recall the details on it.</p> <p>22 Q. Is it your position as you sit</p> <p>23 here today that you know for sure that the</p> <p>24 CIR panel did not -- was not aware of or even</p> <p>25 considered any of the eight studies that you</p> |
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| <p>1 A. If you want me to talk about</p> <p>2 it, you'd have to pull it out for me, but I</p> <p>3 know the name, yes.</p> <p>4 Q. Okay. And it was looking at an</p> <p>5 association between the perineal use of talc</p> <p>6 and ovarian cancer, correct?</p> <p>7 A. That, I'd have to look at it to</p> <p>8 tell you. I believe it was a human study</p> <p>9 that would be consistent with that, but I</p> <p>10 need to pull it out to look at it.</p> <p>11 Q. All right. Do you, as you sit</p> <p>12 here today, do you know why you did not</p> <p>13 discuss it in your report?</p> <p>14 A. I wasn't doing a full causation</p> <p>15 analysis in this report, so as a result I'm</p> <p>16 not trying to characterize every piece of</p> <p>17 human data. But I certainly am looking at</p> <p>18 the consistency across the studies, and</p> <p>19 that's what I've done.</p> <p>20 And I mention it here. I do</p> <p>21 think I mention here that there are studies</p> <p>22 that came to different conclusions than the</p> <p>23 ones that I'm specifically describing.</p> <p>24 Q. Okay. And so why is it that --</p> <p>25 why is it acceptable for you to choose not to</p> | <p>1 contend the omission of which makes it of</p> <p>2 little weight?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I would say I'm</p> <p>5 99.9 percent sure, based on the</p> <p>6 process that is -- that goes in. And</p> <p>7 if you want me to explain, I'll tell</p> <p>8 you why I feel that level of surety.</p> <p>9 You know, I can always say that</p> <p>10 maybe there was someone that came to</p> <p>11 the panel that did a search on their</p> <p>12 own, but that is not what's done. The</p> <p>13 individuals that come to the panel are</p> <p>14 given a body of information provided</p> <p>15 to them in written form that they</p> <p>16 review. So it's not like they -- they</p> <p>17 have access to anything that isn't</p> <p>18 cited in the actual report.</p> <p>19 QUESTIONS BY MS. BRANSCOME:</p> <p>20 Q. Okay. The eight articles that</p> <p>21 you discuss that are not mentioned in the CIR</p> <p>22 panel's work, they are publicly available</p> <p>23 pieces of scientific literature, correct?</p> <p>24 A. Yes, which was why it's</p> <p>25 interesting to me that those were not grabbed</p> |

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| <p>1 and included within -- within the assessment</p> <p>2 done by the -- by the PCPC's group that</p> <p>3 handles CIR -- handled the CIR process here.</p> <p>4 Q. Okay. We received just before</p> <p>5 your deposition, a few days in advance, a</p> <p>6 list of materials that have been added to</p> <p>7 your reliance list since you produced your</p> <p>8 report in this case.</p> <p>9 Did you provide that list of</p> <p>10 materials to counsel to -- are you aware of</p> <p>11 the materials that were identified?</p> <p>12 A. Yes, I am. They're ones that I</p> <p>13 have reviewed since my report and -- yes,</p> <p>14 which would have been, I believed, important</p> <p>15 for you to know about, because obviously you</p> <p>16 wouldn't know if I hadn't provided that to</p> <p>17 you, and fair game for you to ask me about.</p> <p>18 Q. On that list was contained a</p> <p>19 number of news articles.</p> <p>20 A. Uh-huh.</p> <p>21 Q. Are news articles pieces of</p> <p>22 scientific information that you typically</p> <p>23 consider in performing a risk assessment?</p> <p>24 A. No, they're not part of my risk</p> <p>25 assessment, but they -- but they were</p> | <p>1 section on the role of the industry in</p> <p>2 Section 7.</p> <p>3 Q. Okay. So the newspaper</p> <p>4 articles are not something that you are</p> <p>5 considering as part of your analysis of</p> <p>6 whether there is a risk of ovarian cancer</p> <p>7 from Johnson's baby powder, correct?</p> <p>8 A. No, that's a separate issue</p> <p>9 because it's not -- it's not scientific data,</p> <p>10 per se.</p> <p>11 Q. Okay. All right. Now, if you</p> <p>12 could turn to paragraph 31 in your report.</p> <p>13 Okay. You discuss the</p> <p>14 biological effects of talc in this paragraph</p> <p>15 and in others, correct?</p> <p>16 A. Yes, I would call this my</p> <p>17 introductory paragraph to transition into a</p> <p>18 specific topic, yes.</p> <p>19 Q. Okay. And you talk here about</p> <p>20 the structure and size of talc affecting its</p> <p>21 properties.</p> <p>22 What do you mean by that?</p> <p>23 A. So whether it's fibrous enough,</p> <p>24 platy, fibrous. Whether it is particle sizes</p> <p>25 of less than 10 microns, less than 5 microns,</p> |
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| <p>1 relevant to -- they were relevant to my</p> <p>2 overall assessment of the issue of what the</p> <p>3 company is doing with regard to public</p> <p>4 dissemination of information.</p> <p>5 So it's not the risk assessment</p> <p>6 part. It's more on the issue of the -- when</p> <p>7 I talk about the different influences of the</p> <p>8 company on public dissemination of</p> <p>9 information, I went through the different</p> <p>10 specific issues. So this would be a specific</p> <p>11 issue related to a news report that someone</p> <p>12 comes out with, the Reuters report, and then</p> <p>13 looking at what the company is saying in</p> <p>14 addition to that.</p> <p>15 So it's understanding -- for</p> <p>16 example, the documents that Reuters</p> <p>17 discusses, many of those I'm sure I have</p> <p>18 seen, although I don't have access to -- I</p> <p>19 wasn't able to go on websites and download</p> <p>20 everything that they cite. But certainly</p> <p>21 they looked familiar, some of the ones I did</p> <p>22 see.</p> <p>23 So it's that issue of -- the</p> <p>24 last part of my report, I think. Want me to</p> <p>25 tell you the section? It would be in the</p> | <p>1 greater than 75 microns. There's</p> <p>2 different -- certain pieces of literature</p> <p>3 deal with different size ranges of talc. The</p> <p>4 smaller the size range, the more toxic it is,</p> <p>5 for example, to lung tissue; the more likely</p> <p>6 it is to be able to move, based upon the</p> <p>7 size, versus being engulfed by a macrophage</p> <p>8 if it's a larger particle, things like that.</p> <p>9 Q. So focusing specifically on</p> <p>10 ovarian cancer, what role does size and</p> <p>11 structure of a talc particle play with</p> <p>12 respect to a risk of ovarian cancer in your</p> <p>13 opinion?</p> <p>14 A. I don't think I formed a</p> <p>15 opinion that it has to be a specific size or</p> <p>16 structure, because the -- my opinions are</p> <p>17 related to the fact that we have a complex</p> <p>18 mixture of ingredients within the body</p> <p>19 powder, and my assessment's been on the</p> <p>20 overall consumer product, not on any one</p> <p>21 particular ingredient only within it.</p> <p>22 So it's the idea of just</p> <p>23 understanding that size and structure of</p> <p>24 these particles are general principles that</p> <p>25 affect toxicology. So a larger particle or a</p> |

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| <p>1 fibrous particle may have a different tissue 2 toxicity response than a smaller particle. 3 So in other words -- I think I 4 discuss this later in a paragraph about 5 pleurodesis, the idea that you can get acute 6 versus chronic inflammation, or respiratory 7 distress or not. So it's just this idea of a 8 general principle that outlines how you would 9 think about particles generally as a 10 toxicologist. 11 Q. Well, okay. So you said that 12 your assessment is based on the overall 13 consumer product. That would be Johnson's 14 baby powder or SHOWER TO SHOWER®, correct? 15 A. Yes. 16 Q. All right. 17 A. Or Shimmer. I think that's the 18 other name. There's a third product. 19 Q. Okay. But my question to you 20 is, you actually cite a number of pieces of 21 literature in the section about the alleged 22 toxicity of talc that don't relate to the 23 overall consumer products at issue in this 24 case, correct? 25 MS. PARFITT: Objection. Form.</p> | <p>1 known to affect tissue toxicity as far as 2 adverse events like inflammation and/or 3 irritation. 4 Q. Okay. So that's -- that's what 5 I'm trying to understand in more detail. 6 What is your opinion with 7 respect to -- let's take size to start with. 8 Is there a particular size talc particle that 9 is more or less likely to cause inflammation, 10 in your opinion? 11 A. It depends whether you're 12 talking about acute or chronic. I would say 13 for acute inflammation the larger particles, 14 such as some of the particle sizes that are 15 used in the pleurodesis products, are more 16 likely to initiate an acute inflammatory 17 response due to the fact that they're large 18 enough that the body will recognize them with 19 a fairly robust foreign body response. 20 Q. What is your definition of 21 large? 22 A. So the literature varies, but 23 certainly particles that are above -- some of 24 the literature talks about particles that are 25 in the range of 25 to 75. Some of them talk</p> |
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| <p>1 THE WITNESS: No, I would 2 disagree with that when you use the 3 word "relate." Relate to me means is 4 it relevant to the assessment, and 5 they are, even if they're not just on 6 the finished product. 7 But if what you mean is that 8 there are studies that did not test 9 the consumer product but individual 10 ingredients or -- that is true, yes, 11 but all of that is relevant or relates 12 to the overall risk assessment. 13 QUESTIONS BY MS. BRANSCOME: 14 Q. Okay. So given your view that 15 information about the individual constituents 16 is relevant to evaluating the overall 17 toxicity of the ultimate consumer products, 18 then my question to you is: How does the 19 structure and size of the component talc 20 particles play a role in toxicity with 21 respect to ovarian cancer? 22 A. Just generally -- it's not 23 just -- well, with respect to ovarian cancer, 24 we start with irritation, inflammation 25 potential. Size of particles and shape are</p> | <p>1 about larger particles even than that. 2 It has to do with the fact 3 that -- this is complicated by the fact that 4 any consumer product -- or any talc sample 5 will have a range of sizes because they don't 6 select for one size. They select for smaller 7 than. So a 200 mesh, a 400 mesh, that has do 8 with what will filter through. 9 So pleurodesis, they try to 10 avoid for those products the really small -- 11 large amounts of less than 10 because that 12 leads to respiratory distress, whereas many 13 of the consumer talc products are using much 14 smaller, finer particles to get that feel and 15 performance they want from the consumer body 16 powders. 17 Q. Have you reviewed -- focusing 18 specific on Johnson & Johnson's products, 19 have you reviewed the documents that relate 20 to the specifications for the Johnson's 21 products with respect to the size of the 22 plate particles? 23 A. I have seen those, yes. I 24 can't tell you what each of them says without 25 pulling them out, but, yes, that is certainly</p> |

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| <p>1 documents I have seen and relied upon.</p> <p>2 Q. Is it consistent with your</p> <p>3 understanding that it was Johnson & Johnson's</p> <p>4 intention to select large platy talc</p> <p>5 particles for its products?</p> <p>6 MS. PARFITT: Objection to</p> <p>7 form.</p> <p>8 QUESTIONS BY MS. BRANSCOME:</p> <p>9 Q. Have you seen that in the</p> <p>10 documents?</p> <p>11 A. I don't know that it's</p> <p>12 described quite that way, but they certainly</p> <p>13 were doing a 200 mesh selection. So -- for</p> <p>14 their body powders products. So -- and they</p> <p>15 were trying -- and they did make attempts to</p> <p>16 look for sources that were more platy talc</p> <p>17 than other forms, but that doesn't ensure</p> <p>18 that everything is platy talc.</p> <p>19 Q. Are you familiar with the term</p> <p>20 "fines"?</p> <p>21 A. Yes, generally, but I'm not --</p> <p>22 but I'm not an expert in the processing of</p> <p>23 talc as far as how you would go about</p> <p>24 choosing an ore or a mine. There's others</p> <p>25 that will be addressing that. That's not my</p> | <p>1 effects that beneficiation can have on the</p> <p>2 level of the component -- the components in</p> <p>3 talc and what ultimately ends up in one of</p> <p>4 Johnson & Johnson's consumer products?</p> <p>5 MR. MEADOWS: Objection.</p> <p>6 THE WITNESS: So I'm not -- I'm</p> <p>7 not familiar with all the details, but</p> <p>8 I am familiar that it is a process</p> <p>9 they're using to attempt to result in</p> <p>10 a product that has characteristics</p> <p>11 that would be desirable for a consumer</p> <p>12 product.</p> <p>13 Again, there is my</p> <p>14 understanding that others are going to</p> <p>15 be discussing the geology or the</p> <p>16 processing, and that is not something</p> <p>17 I'm looking at.</p> <p>18 The literature as it relates to</p> <p>19 what has been tested in the public</p> <p>20 literature in particular, and that</p> <p>21 would be either an ingredient or a --</p> <p>22 or a consumer product or a -- they may</p> <p>23 discuss exposure occupationally to</p> <p>24 mining or milling, which is -- which</p> <p>25 is an issue that you can consider when</p> |
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| <p>1 area.</p> <p>2 Q. What is your understanding of</p> <p>3 the term "fines"?</p> <p>4 A. My understanding of the term</p> <p>5 "fines" has to be looking for a sample or a</p> <p>6 group that has been processed such that it</p> <p>7 has certain characteristics.</p> <p>8 Other than that, I would refer</p> <p>9 you to the individuals in litigation that are</p> <p>10 going to be dealing with the processing.</p> <p>11 Q. Okay. Have you taken into</p> <p>12 account in your analysis in any way the</p> <p>13 beneficiation process that occurs between the</p> <p>14 time that the talc is mined and it ends up in</p> <p>15 one of the consumer products that is relevant</p> <p>16 to your analysis?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: So what do you</p> <p>19 mean by taking it into account? Am I</p> <p>20 aware that they have something that's</p> <p>21 in place for that? Yes.</p> <p>22 But take into account, what do</p> <p>23 you mean by that?</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. Are you familiar with the</p> | <p>1 you're reviewing that literature as</p> <p>2 well.</p> <p>3 QUESTIONS BY MS. BRANSCOME:</p> <p>4 Q. Okay. And so when you cite --</p> <p>5 for example, you have a significant number</p> <p>6 of -- I'm trying to find the right paragraph.</p> <p>7 You have a section in your</p> <p>8 report where you discuss a number of</p> <p>9 different articles that relate to talc, and</p> <p>10 in parentheses you identify that the talc</p> <p>11 source might be cosmetic, it might be</p> <p>12 industrial, things of that nature, correct?</p> <p>13 A. Yes, I do that on purpose</p> <p>14 because I wanted -- I did look at the</p> <p>15 literature to understand what they were --</p> <p>16 what they were -- what type of exposure they</p> <p>17 were describing.</p> <p>18 Q. Okay. And so understanding</p> <p>19 that some of those products are not</p> <p>20 representative of what ultimately is in</p> <p>21 Johnson's baby powder, do you have anything</p> <p>22 in your report that explains how you did or</p> <p>23 did not give weight to those particular</p> <p>24 studies?</p> <p>25 MS. PARFITT: Objection. Form.</p> |

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| <p>1 THE WITNESS: Let me look and 2 see what I say. 3 If the question has to do with 4 numerical rankings, no, I did not do 5 that. But you're asking something 6 else, right, broader than that, 7 correct? 8 QUESTIONS BY MS. BRANSCOME: 9 Q. The question that I have is, 10 how did -- is there somewhere in this report 11 that I can understand the weight that you 12 assigned to say a study that related to 13 industrial talc as opposed to information 14 about cosmetic talc, for example? 15 MR. MEADOWS: Objection. 16 THE WITNESS: So I -- I'm -- I 17 believe I address that. I don't know 18 it's exactly answering your question, 19 but I lay out for you the 20 characteristics of the literature in 21 paragraph 37, and I point out that the 22 scientific literature varies. 23 And the fact -- and I point -- 24 and I admit -- I'm not admitting. I'm 25 stating the fact that in some cases</p> | <p>1 something that ever ended up in Johnson's 2 products, correct? 3 MR. MEADOWS: Objection. 4 THE WITNESS: I don't think I 5 can answer that yes or no. I haven't 6 done an assessment to see whether it 7 ever ended up in the products. That's 8 a different question. 9 I certainly am aware of the 10 fact that was not a primary source of 11 their talc, that is true. I do know 12 that. 13 In other words, I don't have 14 records from -- going back from 1894 15 on what the source of their talc was. 16 So I can't tell you over time. 17 What I do know, what's been put 18 into depositions and testimony of 19 company employees more recently, where 20 it's my understanding that the 21 principal sources over the years were 22 either the Vermont mine, the Italian 23 mine or the Chinese mine. And there 24 were different interruptions in time 25 where different mines were used,</p> |
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| <p>1 the authors will not describe it 2 specifically as the type of talc, but 3 just talc, whereas -- with no 4 description of purity or state, for 5 example. But in cases where the 6 literature does, I did consider that 7 in my weight of the evidence. 8 So, for example, when I -- when 9 I lay it out here in these bullets 10 where I'm putting for you tremolite 11 mining industrial grade cosmetic, it 12 certainly is something that I weighed. 13 And obviously as much information as I 14 can get on cosmetic-grade talc is 15 going to be most important in the 16 assessment, but that doesn't mean the 17 other information isn't relevant. 18 You want me to explain why? 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Well, so, for example, you 21 describe the Dreessen article that related to 22 trimellitic talc that's mined out of 23 New York. 24 You would agree that 25 trimellitic talc from New York is not</p> | <p>1 depending on sourcing. 2 QUESTIONS BY MS. BRANSCOME: 3 Q. So as part of your expert 4 analysis where you are evaluating articles 5 that relate to different types of talc from 6 different sources of talc, have you done an 7 analysis of how those particular types of 8 talc do or do not relate to what is in the 9 consumer product manufactured by Johnson & 10 Johnson? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: The first part of 13 your question, again? I'm sorry. 14 MS. BRANSCOME: Would you read 15 it back? 16 THE WITNESS: Could you read it 17 back to me again? I didn't mean to 18 wander, but the first few words I 19 missed. 20 (Court Reporter read back 21 question.) 22 THE WITNESS: Okay. So I 23 certainly did, which is why I'm 24 breaking this out here for you this 25 way.</p> |

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| <p>1 So I am -- I am certainly</p> <p>2 recognizing, and I analyzed on the</p> <p>3 paper -- through the papers what type</p> <p>4 of product, if available, that the</p> <p>5 data is on.</p> <p>6 But if you read my report in</p> <p>7 the process of risk assessment, all of</p> <p>8 these categories of papers are</p> <p>9 relevant to telling you something</p> <p>10 about what talc can do. And then when</p> <p>11 you talk about drawing final</p> <p>12 conclusions, I'm looking for</p> <p>13 information, if I can, and I have it,</p> <p>14 that is on point to the product that</p> <p>15 was sold.</p> <p>16 So certainly the studies that</p> <p>17 give me information on cosmetic-grade</p> <p>18 talc are extremely important to my</p> <p>19 assessment, and they're ones that I've</p> <p>20 discussed or we've even used in trial</p> <p>21 before when we've talked about putting</p> <p>22 together a timeline.</p> <p>23 That's what this is about, by</p> <p>24 the way. This discussion here, I'm</p> <p>25 starting to lay out what information</p> | <p>1 that to draw conclusions based upon</p> <p>2 what was available for me to assess.</p> <p>3 QUESTIONS BY MS. BRANSCOME:</p> <p>4 Q. Okay.</p> <p>5 A. I don't know how else to answer</p> <p>6 it for you. That's what the section is meant</p> <p>7 to do, and that's why I broke it out that</p> <p>8 way. You know, I recognize that there is</p> <p>9 data on different things.</p> <p>10 What's interesting about even</p> <p>11 the data on different things, there's a</p> <p>12 common mechanism that is involved with the</p> <p>13 type of tissue toxicity you get, and that's</p> <p>14 irritation and inflammation. Regardless of</p> <p>15 whether it is of a certain grade or not, you</p> <p>16 get certain types of adverse reactions. May</p> <p>17 be a more sustained reaction with a</p> <p>18 industrial grade versus cosmetic grade, but</p> <p>19 they all have the capability to produce that</p> <p>20 type of adverse effect.</p> <p>21 Q. Dr. Plunkett, where can you</p> <p>22 point me to in your report that you discuss</p> <p>23 the weight that you give studies that relate</p> <p>24 to talc from New York as opposed to studies</p> <p>25 that relate to cosmetic talc that ultimately</p> |
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| <p>1 was available over time, and that's</p> <p>2 simply what this is. It's a survey of</p> <p>3 the literature that talks about</p> <p>4 adverse effects of talc, and if I can,</p> <p>5 I separate it into different qualities</p> <p>6 or purities.</p> <p>7 QUESTIONS BY MS. BRANSCOME:</p> <p>8 Q. Dr. Plunkett, respectfully, I</p> <p>9 don't believe you answered my question.</p> <p>10 Can you point me to anywhere in</p> <p>11 your expert report that's been produced in</p> <p>12 this MDL where you do an analysis of how the</p> <p>13 different talc types and sources that you are</p> <p>14 citing as support for the toxicity of talc</p> <p>15 generally relate to the products manufactured</p> <p>16 by Johnson & Johnson?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: So I don't know</p> <p>19 how else to answer that but to tell</p> <p>20 you I think that's what this whole</p> <p>21 section is about. I step you</p> <p>22 through -- I identify different types</p> <p>23 of evidence. I identify for you what</p> <p>24 was tested in those different pieces</p> <p>25 of evidence, and then I step through</p> | <p>1 ended up in Johnson's baby powder?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: I've tried to</p> <p>4 answer that for you. The weight that</p> <p>5 I'm giving -- the weight that I'm</p> <p>6 giving is part of my assessment. So,</p> <p>7 again, I don't give numerical</p> <p>8 rankings. I've answered that for you.</p> <p>9 I don't do that.</p> <p>10 What I instead do is I'm</p> <p>11 looking at everything that's relevant,</p> <p>12 everything that's available. I do</p> <p>13 categorize it, so I am selecting -- I</p> <p>14 am identifying or analyzing the</p> <p>15 information for what it describes.</p> <p>16 And then if you go further on down, I</p> <p>17 try to tell you what I think is</p> <p>18 important about that information.</p> <p>19 The overall conclusions I'm</p> <p>20 drawing in the report, though, when I</p> <p>21 cite to specific studies in the risk</p> <p>22 assessment, the majority of those</p> <p>23 studies I believe that I'm citing for</p> <p>24 you, outside of notice, have to do</p> <p>25 with -- that's more of a warnings</p> |

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| <p>1 issue -- have to do with the issue of 2 cosmetic talc. Because the human 3 studies are describing cosmetic talc. 4 The NTP studies is a pure talc. Many 5 of the in vitro studies and other 6 animal studies are looking at, 7 quote/unquote, a talc that is not an 8 industrial grade or from a mine that 9 would have -- be looked at in that 10 way. So -- 11 QUESTIONS BY MS. BRANSCOME: 12 Q. You understand that there are 13 different types of cosmetic talc, correct? 14 A. Yes, I am aware. 15 Q. And cosmetic talc can be mined 16 from a number of different mines globally, 17 correct? 18 A. That's correct. 19 Q. And some of the studies that 20 you cite in your report are testing cosmetic 21 talc from other consumer products, for 22 example, Cashmere Bouquet, correct? 23 A. Some. The majority of them are 24 not, but I would agree that some do, yes. 25 Q. Okay. Have you done an</p> | <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. I was simply asking: Did you 3 do an analysis that would allow you to 4 compare the ingredients in another product, 5 like consumer Cashmere Bouquet, before you 6 rendered an opinion with respect to Johnson's 7 baby powder based on tests of Cashmere 8 Bouquet? Did you do that analysis? 9 MR. MEADOWS: Objection. 10 THE WITNESS: I do not have 11 access to internal company documents 12 for the manufacturers of Cashmere 13 Bouquet, so I certainly couldn't do 14 the analysis in the same way that I 15 can do it here, where I can identify 16 what Johnson & Johnson and Imerys 17 describe as sources of the talc that 18 was used for the Johnson & Johnson 19 baby powder, without -- 20 QUESTIONS BY MS. BRANSCOME: 21 Q. So you have no way of knowing 22 one way or the other whether that talc is 23 similar, correct? 24 MR. MEADOWS: Objection. 25 MS. PARFITT: Objection.</p> |
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| <p>1 analysis of how the talc that is used in 2 Cashmere Bouquet, for example, relates to the 3 talc that is used in Johnson's baby powder? 4 Is that an analysis that you 5 have done before relying on that information 6 in your report? 7 MR. MEADOWS: Objection. 8 MS. PARFITT: Objection. 9 THE WITNESS: My analysis -- I 10 did do an analysis to look at what was 11 described, what products are 12 described, but I certainly -- I 13 certainly did not throw out studies 14 that described Cashmere Bouquet 15 because I would -- I still believe as 16 a toxicologist and a risk assessor 17 that those types of products are 18 important to the overall weight of the 19 evidence about the hazard and the 20 risks posed by talc. 21 You know, I just -- I just -- I 22 guess I disagree with you if you're 23 saying they're irrelevant. I don't 24 believe that they are. 25</p> | <p>1 THE WITNESS: Well, I think I 2 do know it's similar, if you look on 3 the bottle as far as what is described 4 it being, but if you're asking me -- 5 if you're asking did we fingerprint it 6 to only a particular mine, this is the 7 beauty of the data. The data shows 8 that regardless of the type of product 9 you're looking at, there's consistency 10 across the study. 11 So -- but I did not try to 12 segregate out studies that only dealt 13 with Cashmere Bouquet, no, I did not 14 do that. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. Okay. As you sit here today as 17 a toxicologist, is it your position that 18 industrial-grade talc that might contain up 19 to 70 percent tremolite presents the same 20 level of toxic effect as cosmetic talc that 21 may contain no tremolite or tremolite at a 22 very, very low level? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I haven't formed 25 that opinion, no.</p> |

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| <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. And so have you formed 3 an opinion that I could find in your report 4 that discusses in any way the relative 5 toxicity of different types of talc? 6 A. That, you may find. I need to 7 go back and look how I set it out, but I 8 think I -- I talked with you about the 9 difference between fibrous versus platy. I 10 do discuss that. 11 And I talk about the problems 12 when you have a complex mixture that has 13 added to it things like asbestos and heavy 14 metals, because I talk about the additivity 15 issue that can come to play. So that -- in 16 other words, increased risk when you have a 17 complex mixture with additional components 18 that all share the same toxic properties as 19 far as target organs or types of effects or 20 mechanisms that are triggered in the body. 21 That's what I point you to. 22 I -- I don't -- that's the only 23 way I can answer that for you, I think, based 24 on what I know I have in here. 25 Q. Okay. You talk about the term</p> | <p>1 identified characteristics. 2 There's -- within the 3 asbestos -- the asbestos literature 4 there's -- it's one of the forms -- forms of 5 asbestos that's described. For example, in 6 IARC, they describe all of the ones that have 7 carcinogenic properties. It's one of them. 8 Within the literature within 9 Johnson & Johnson's documents, there's 10 tremolite discussed as -- I assume them 11 referring to asbestos tremolite, asbestos in 12 a tremolite characteristic. I have seen 13 tremolite talc also mentioned in the 14 literature. 15 If you want a specific 16 discussion of each of those, again, 17 there's -- I understand there's experts that 18 are going to describe the distinguishing 19 characteristics of each of those. 20 I'm only setting out this is 21 what I have seen, talked about, in the 22 literature. 23 Q. So you are not an expert on the 24 differences between fibrous talc, asbestiform 25 talc, non-asbestiform talc and tremolite as</p> |
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| <p>1 "asbestiform talc." 2 You talk about asbestiform 3 talc. 4 Are you familiar with that? 5 A. I do mention that in my report, 6 yes. 7 Where are you? 8 Q. At paragraph 30. It's on 9 page 19 of your report. 10 A. Yes, I'm here. 11 Q. Okay. And the first sentence 12 in paragraph 30 you state, "In the published 13 medical literature, there is often discussion 14 of talc using terms such as fibrous talc, 15 asbestiform talc, non-asbestiform talc or 16 tremolite." 17 Do you see that? 18 A. Yes, I do. 19 Q. Okay. Is it your opinion that 20 tremolite is a form of talc? 21 A. So tremolite is a -- is a -- is 22 a type of fiber or a -- tremolite is a -- is 23 a substance or a entity that has been 24 identified as a specific morphology, I guess, 25 identified characteristics of a -- it has</p> | <p>1 it relates to toxicity. Is that your opinion 2 today? 3 A. No, that's not what I'm saying. 4 I'm saying that if you want me to -- I'm -- 5 if you want me to describe the 6 characteristics and the morphology of each of 7 those individually, that's something a 8 geologist would do. 9 But certainly as far as the 10 toxicity assessment I did, each of these 11 types of -- each of these words, I guess, or 12 names have been applied in the literature 13 when they talk about toxicity of talc. Some 14 of the literature talks about fibrous talc or 15 just -- other literature just talks about 16 talc. Some of it, for example, the IARC 17 monographs, distinguish between asbestiform 18 talc and non-asbestiform talc in their 19 assessments of the cancer risk. 20 And then tremolite is discussed 21 as a component of talc. And I have seen 22 papers that talk about tremolite -- 23 nontremolite talc or tremolite-containing 24 talc. That's how you most often see it. 25 So it's the idea that it is a</p> |

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| <p>1 constituent of certain mines that -- and</p> <p>2 that's my understanding of it. But if you</p> <p>3 want -- and they all -- they all certainly do</p> <p>4 show that the toxicity can be affected,</p> <p>5 whether it's a fiber or a platy particle. So</p> <p>6 tremolite being a fiber would certainly</p> <p>7 affect my overall assessment of risk. The</p> <p>8 more tremolite that you would have would</p> <p>9 make -- would make it more likely to be</p> <p>10 reactive in terms of a foreign body response,</p> <p>11 depending on the size.</p> <p>12 Q. What's your basis for saying</p> <p>13 that?</p> <p>14 A. That's based on a fibrous form</p> <p>15 versus a platy particle form. That's the</p> <p>16 issue of -- I have that paragraph where I</p> <p>17 talk about what macrophages look for, can</p> <p>18 engulf or not engulf. So those are all</p> <p>19 things that are important to a toxicologist</p> <p>20 to understand exist.</p> <p>21 But certainly within my</p> <p>22 assessment I have to include literature from</p> <p>23 all of those because of the fact that all of</p> <p>24 those are relevant to the toxicity profile,</p> <p>25 since I know that the cosmetic baby powders</p> | <p>1 Q. Okay. And so when you're</p> <p>2 looking at a complex mixture, you would agree</p> <p>3 as a toxicologist it would be important to</p> <p>4 understand the constituent elements of that</p> <p>5 mixture, correct?</p> <p>6 A. Yes, it is important to</p> <p>7 understand that this is -- what is in the</p> <p>8 mixture, and that's -- that's part of what I</p> <p>9 try to do.</p> <p>10 Q. Okay. And it would be</p> <p>11 important before drawing conclusions from one</p> <p>12 study that might have different constituent</p> <p>13 components, it's important to understand the</p> <p>14 relative toxicity of individual constituent</p> <p>15 elements, correct?</p> <p>16 A. Depends if you can or not. I</p> <p>17 mean, there's certain types of studies you</p> <p>18 can, where in the published literature that's</p> <p>19 been described. That's why I'm pointing this</p> <p>20 out. It's the idea that within the</p> <p>21 literature, when you go through, it's</p> <p>22 important to understand what you can say</p> <p>23 about the consistency across the literature</p> <p>24 where maybe different types of talc are</p> <p>25 discussed.</p> |
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| <p>1 and the data I've seen shows detection of</p> <p>2 something called fibrous talc.</p> <p>3 I see detection of tremolite</p> <p>4 within certain samples of baby powder.</p> <p>5 And then I have just the</p> <p>6 general category of asbestiform versus</p> <p>7 non-asbestiform when I consider the way, for</p> <p>8 example, IARC has reviewed the</p> <p>9 carcinogenicity.</p> <p>10 So those are -- those are terms</p> <p>11 that I'm laying out because I think they are</p> <p>12 something you need to understand exists in</p> <p>13 the literature.</p> <p>14 Q. Okay. But I'm trying to</p> <p>15 understand, not helping me understand the</p> <p>16 literature. I'm trying to understand your</p> <p>17 opinions with respect to toxicity.</p> <p>18 Is it, for example, your</p> <p>19 opinion that fibrous talc has the same toxic</p> <p>20 potential -- let's focus specifically with</p> <p>21 respect to ovarian cancer -- as tremolite?</p> <p>22 A. I haven't formed that opinion,</p> <p>23 but, again, I would -- my opinion has been</p> <p>24 formed on the fact that we have complex</p> <p>25 mixture that includes all of these things.</p> | <p>1 And that's what I -- I think I</p> <p>2 lay out for you. I tell you there's</p> <p>3 consistency in certain toxic effects that are</p> <p>4 seen. Regardless of the form that you're</p> <p>5 looking at, talc has certain properties, and</p> <p>6 all of these things are -- been shown to be</p> <p>7 in the complex mixture, so I have -- as a</p> <p>8 result, all of that literature has relevance</p> <p>9 to at least the hazard part of my assessment,</p> <p>10 and certainly have relevance to -- when you</p> <p>11 want to talk about warning and the final risk</p> <p>12 assessment, they're definitely relevant, but</p> <p>13 certainly the -- when I go through this</p> <p>14 process, I am trying to focus as much as I</p> <p>15 can on a product that is most similar to the</p> <p>16 one I'm assessing.</p> <p>17 So obviously that's why --</p> <p>18 that's one of the reasons I do look at the</p> <p>19 human data, because the human data is</p> <p>20 involving a consumer product use, which is</p> <p>21 what I'm talking about here.</p> <p>22 Q. Is it using specifically</p> <p>23 Johnson's baby powder?</p> <p>24 A. Many of them are, yes.</p> <p>25 Q. Okay.</p> |

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| <p>1 A. Based on my understanding of 2 what I see discussed within the literature. 3 Q. Did you identify in your report 4 specifically which report -- which studies 5 have used a consumer product manufactured by 6 Johnson & Johnson? 7 A. I haven't laid them out 8 individually, no, but I am aware of 9 discussions of this general issue within some 10 of the documents I've seen, and essentially 11 Johnson's body powders products were the 12 overwhelming share of the market. 13 Q. But you would agree that 14 studies that did not involve the consumer 15 product manufactured by Johnson & Johnson 16 should be given less weight when analyzing 17 whether or not there are risks associated 18 specifically with Johnson & Johnson's 19 products? 20 MS. PARFITT: Objection. Form. 21 MR. MEADOWS: Objection. 22 THE WITNESS: It depends on the 23 question being asked within the 24 assessment, the risk assessment. It 25 really does, I mean, because each of</p> | <p>1 across the studies that are dealing 2 with not the consumer product but 3 other descriptions, there is a 4 consistency in the types of effects 5 you see. 6 And since I'm not quantifying 7 the risk but identifying it as being 8 increased or not, in other words, is 9 it more likely than not that someone 10 exposed in this way could be at a risk 11 of ovarian cancer, that's what I'm 12 talking about. 13 So again, it's -- if I was 14 trying to identify differences in 15 cancer potency factors for different 16 types, then, yes, if I had an animal 17 study on each of those, I could 18 compare potency for cancer, but that 19 hasn't been done. 20 QUESTIONS BY MS. BRANSCOME: 21 Q. Okay. 22 A. So instead, what I have to do 23 is rely on what is available to me. And 24 based on my judgment, that's how I review the 25 studies.</p> |
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| <p>1 these studies brings a piece of 2 evidence to the risk assessment. 3 And so the question is -- for 4 each one, you consider it on a 5 case-by-case basis. It is possible, 6 yes, that you would give less weight. 7 It's also possible that you would not, 8 dependent upon what you know about 9 that study and how it relates to other 10 studies that are out there. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. So methodologically, how would 13 I understand from your report marked as 14 Exhibit 4 under what circumstances to give a 15 study that relates to, for example, 16 industrial talc less weight than a study that 17 actually used Johnson's baby powder? 18 MR. MEADOWS: Objection. 19 THE WITNESS: Well, I've tried 20 to tell you that. That's what I said 21 for you. That's why I am doing it. I 22 certainly am trying to focus in on 23 studies that deal with the consumer 24 product. 25 But what I find when I look</p> | <p>1 Q. And so for the opinions that 2 you are offering in the MDL, you agree that 3 you are not quantifying the risk associated 4 with Johnson's baby powder, SHOWER TO SHOWER® 5 or Shimmer with respect to the potential for 6 causing ovarian cancer? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: In terms of a 9 cancer potency factor, that is true, I 10 am not. Instead, what I am doing is I 11 am quantifying whether or not I 12 believe that the risk is increased 13 above a background risk. 14 That has to do with -- that's 15 where I bring in, in my risk 16 assessment, the human data, because 17 the human data is showing 18 statistically significant increases in 19 risk in populations using the consumer 20 product. 21 So I have a quantification 22 where I'm using the word "increased," 23 and I believe to a reasonable degree 24 of medical certainty that indeed the 25 risk is increased. So I'm quantifying</p> |

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| <p>1 in that way, but I'm not giving it a</p> <p>2 number. I'm not saying that the</p> <p>3 cancer potency factor is such that you</p> <p>4 increase the risk from one in a</p> <p>5 million to 10 in a million to 1 in a</p> <p>6 thousand. That I have not done</p> <p>7 because I don't have the data, the</p> <p>8 studies. The company has not done</p> <p>9 studies on each of these to allow me</p> <p>10 to do that.</p> <p>11 QUESTIONS BY MS. BRANSCOME:</p> <p>12 Q. Okay. The reference that you</p> <p>13 made to the human data that you believe shows</p> <p>14 a statistically increased risk in populations</p> <p>15 using the consumer product, have -- which --</p> <p>16 have you identified in your report which of</p> <p>17 those studies are specifically using a</p> <p>18 product that was manufactured by Johnson &</p> <p>19 Johnson?</p> <p>20 A. I don't lay that out for my</p> <p>21 report, I do not, but certainly it is</p> <p>22 something that for some of the studies I</p> <p>23 believe you can -- you might be able to get</p> <p>24 some of that information from. But certainly</p> <p>25 I have not laid that out individually in my</p> | <p>1 QUESTIONS BY MS. BRANSCOME:</p> <p>2 Q. In reaching your opinion in the</p> <p>3 MDL that there is an increased risk above</p> <p>4 background of ovarian cancer from the use of</p> <p>5 products manufactured by Johnson & Johnson,</p> <p>6 have you made an attempt to identify</p> <p>7 specifically which studies, the human studies</p> <p>8 on which you rely, test or look at people who</p> <p>9 have used Johnson & Johnson's products?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 THE WITNESS: It's my -- my</p> <p>12 review of the study indicates that I</p> <p>13 would say for the vast majority of</p> <p>14 them you cannot do that.</p> <p>15 But you can take what is</p> <p>16 reported and look at things such as</p> <p>17 market share and those kind of things</p> <p>18 to get an idea of what you believe the</p> <p>19 exposure would have been.</p> <p>20 But certainly I have not -- I</p> <p>21 have not tried to apply some kind of a</p> <p>22 numerical value to how many people in</p> <p>23 the study may have used Johnson's baby</p> <p>24 powder or not, no, that has not been</p> <p>25 done. I don't think anybody -- any of</p> |
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| <p>1 report, no.</p> <p>2 Q. And you would agree that for</p> <p>3 some of those studies there is no information</p> <p>4 as to the specific type of consumer talc that</p> <p>5 the individuals who are being studied used,</p> <p>6 correct?</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: I would agree</p> <p>9 that in some of those studies they're</p> <p>10 not saying, but that is why you look</p> <p>11 at the evidence overall.</p> <p>12 And what's important to look at</p> <p>13 in terms of now -- if you wanted to go</p> <p>14 to Bradford Hill, that's why you look</p> <p>15 at things such as consistency. So</p> <p>16 what do the studies show. We see a</p> <p>17 certain level of increased risk across</p> <p>18 studies, regardless of who did the</p> <p>19 study or what population was being</p> <p>20 looked at.</p> <p>21 So that's the best way I can</p> <p>22 answer that for you. That is -- that</p> <p>23 is part of the -- of the assessment</p> <p>24 that you look at.</p> <p>25</p> | <p>1 the bodies that have looked at this</p> <p>2 have done that.</p> <p>3 QUESTIONS BY MS. BRANSCOME:</p> <p>4 Q. You have not done a market</p> <p>5 share analysis, correct?</p> <p>6 A. No, I've seen this in documents</p> <p>7 only. I have not done my own. There are</p> <p>8 company documents that talk about their</p> <p>9 market share.</p> <p>10 Q. Okay. Have you made an attempt</p> <p>11 to examine the levels of fibrous talc or</p> <p>12 asbestiform talc that are in different</p> <p>13 consumer products, aside from Johnson's baby</p> <p>14 powder or SHOWER TO SHOWER® or Shimmer?</p> <p>15 A. So for that are you referring</p> <p>16 to things such as -- other types of cosmetics</p> <p>17 like foundations or lipsticks or --</p> <p>18 Q. I'll rephrase.</p> <p>19 Have you made any attempt to</p> <p>20 examine whether other cosmetic talc body</p> <p>21 powders have a different percentage of</p> <p>22 fibrous, or what you refer to as asbestiform</p> <p>23 talc, from the Johnson & Johnson products?</p> <p>24 Have you done any analysis to</p> <p>25 make that comparison one way or the other?</p> |

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| <p>1 MS. PARFITT: Objection. Form.</p> <p>2 THE WITNESS: I certainly</p> <p>3 haven't done -- I certainly didn't do</p> <p>4 a directed analysis to try to</p> <p>5 determine that, but there is</p> <p>6 information, I believe, in -- I think</p> <p>7 if you look at some of Dr. Longo's</p> <p>8 work, that may be there.</p> <p>9 And I believe in Dr. Blount's</p> <p>10 published paper there may be a</p> <p>11 discussion of the type of powder</p> <p>12 product used, where she was looking</p> <p>13 for -- at least for asbestiform --</p> <p>14 asbestos within the talc. It may be</p> <p>15 tremolite as well, but -- if you want</p> <p>16 me to look, I can do that. I just</p> <p>17 don't recall whether -- I think she</p> <p>18 did talk about sources of the talc,</p> <p>19 where it came from, so...</p> <p>20 QUESTIONS BY MS. BRANSCOME:</p> <p>21 Q. Okay. But as you sit here</p> <p>22 today, you can't point me to any analysis</p> <p>23 that you did or an analysis that you relied</p> <p>24 on that would relate different brands of</p> <p>25 cosmetic talc body powders with respect to</p> | <p>1 that I state for you that it's my</p> <p>2 opinion that Cashmere Bouquet has this</p> <p>3 specific pattern of constituents as</p> <p>4 compared to Johnson & Johnson's. No,</p> <p>5 I have not done that.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Okay. And that would be true</p> <p>8 for any other brand of cosmetic talc, body</p> <p>9 powders, Jean Nate, Lily of the Valley, not</p> <p>10 just Cashmere Bouquet, correct?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: That is correct,</p> <p>13 I don't have access to that</p> <p>14 information.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. Have you done any analysis of</p> <p>17 the constituent components of talc and how</p> <p>18 they have changed even within Johnson's --</p> <p>19 Johnson & Johnson's manufactured products,</p> <p>20 how the constituents of the consumer products</p> <p>21 may or may not have changed over time?</p> <p>22 A. I've done some of that, yes,</p> <p>23 and I laid that out, I think, for you, when I</p> <p>24 talk about the differences in the products</p> <p>25 that are described within the documents, the</p> |
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| <p>1 their constituent components?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 Completely misstates her testimony.</p> <p>4 She mentioned Dr. Blount. She</p> <p>5 mentioned others.</p> <p>6 THE WITNESS: So I think what I</p> <p>7 started with, I said I haven't done a</p> <p>8 directed analysis to try to determine</p> <p>9 specifically how this product versus</p> <p>10 this product versus this product may</p> <p>11 have looked over time, because I don't</p> <p>12 have access to a full data to do that.</p> <p>13 But what I do have is data that</p> <p>14 has -- I do see published data, for</p> <p>15 example, Blount and maybe some of the</p> <p>16 other published studies, that looked</p> <p>17 at this issue, at least of asbestos</p> <p>18 presence in talc. And I believe</p> <p>19 Dr. Longo also had things that weren't</p> <p>20 just Johnson's. I believe he had</p> <p>21 Cashmere Bouquet, for example, samples</p> <p>22 in some of the things he looked at.</p> <p>23 So I can point you to those</p> <p>24 things that I have reviewed, but I</p> <p>25 haven't -- there's nowhere in here</p> | <p>1 company documents, from the '70s versus the</p> <p>2 '80s versus later on, as far as the changes</p> <p>3 that were made to specifications of the</p> <p>4 product, for example. That's something --</p> <p>5 and I think I've talked about that a bit at</p> <p>6 trial as well.</p> <p>7 Q. Okay. And is it your view that</p> <p>8 the risk potential for Johnson & Johnson's</p> <p>9 manufactured products have changed at all</p> <p>10 over time with respect to ovarian cancer?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: I have not -- I</p> <p>13 have not attempted to differentiate a</p> <p>14 risk potential at only one point in</p> <p>15 time.</p> <p>16 What I have done over points of</p> <p>17 time is looked at the issue of</p> <p>18 warnings and what should be warned</p> <p>19 about.</p> <p>20 But my analysis related to the</p> <p>21 hazard or the risk assessment of the</p> <p>22 products is considering all of the</p> <p>23 available information, which would be</p> <p>24 all of that information over time.</p> <p>25</p> |

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| <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. You talk about, in 3 paragraph 35 primarily -- we'll talk about 4 the fragrance components in more detail, but 5 you talk about the idea of chemicals being a 6 potential irritant. 7 Are you familiar with that? 8 A. Yes, that's correct. 9 Q. Is it your position that any 10 product that contains chemicals that could be 11 an irritant should be labeled with a health 12 warning? 13 MS. PARFITT: Objection. 14 MR. MEADOWS: Okay. 15 THE WITNESS: I don't think 16 that's -- no, I don't think I've 17 formed that specific opinion. 18 But the opinion that I think 19 I'm expressing here is that when you 20 have a -- the information that I have, 21 which unfortunately the company hasn't 22 given us percentages or actual levels, 23 instead, what I do as a toxicologist, 24 I look at what is there. And when I 25 see over a hundred chemicals there,</p> | <p>1 you with specific percentages, and so I'm 2 asking you, is that something that as a 3 toxicologist would be important information 4 to you? 5 A. Depends. Certainly with the 6 fragrance -- and I'm talking about the 7 conversation about this paragraph is focusing 8 on the fragrance components. 9 So, yes, I mention that it 10 would be nice to know, it would be good to 11 know, if we could, exactly what was in there, 12 because I could quantify the hazard or 13 quantify the risk, actually. So instead, I 14 have -- I identify it as a hazard, but I 15 can't quantify it without those levels. 16 But does that change -- make a 17 difference in the overall conclusions I draw? 18 No, it doesn't affect the overall conclusions 19 that I have drawn, but it adds that other 20 piece of the puzzle that deals with the fact 21 that we have a complex mixture that have a 22 combination of ingredients that target 23 irritation. 24 And irritation and the 25 potential to produce an inflammatory</p> |
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| <p>1 that 70 percent of them have been 2 linked as an irritant hazard, there is 3 the issue of toxicological additivity 4 to consider. 5 So certainly as a risk 6 assessor, when I have that many 7 potential sources of irritation as far 8 as chemicals going into a complex 9 mixture, certainly I think I have 10 formed the opinion that I think that 11 is something that needs to be 12 considered when you're talking about 13 providing information to consumers, 14 yes. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. As a toxicologist, would it be 17 important to you to understand the exact 18 percentages of all of the constituent 19 components of, say, Johnson's baby powder, 20 for example? 21 A. Are you talking about just the 22 fragrance or are you talking about everything 23 that's in it? 24 Q. Dr. Plunkett, you referenced 25 the fact that the company has not provided</p> | <p>1 response, in my -- if you've read my report, 2 you understand that I think that's a key 3 factor in increasing the risk for ovarian 4 cancer. 5 Q. Understanding the percentages 6 of the constituent components, is that 7 limited only to fragrance, or would it also 8 be important to understand the percentages 9 for the heavy metals that you contend are in 10 Johnson's baby powder? 11 A. So if I was trying to define 12 the hazard of each component, I would 13 certainly want one to know that. As a 14 result, what I'm doing instead is looking at 15 the complex mixture. In other words, this is 16 a mixture of all these things. 17 I break out those individual 18 components, or constituents, to tell you 19 about the hazard that is brought to play or 20 the toxicity profiles that exists. And 21 what's important about that in my overall 22 evaluation of the end product, which is what 23 my risk assessment is based on, the end 24 product, shows that I have multiple 25 components with similar types of effects.</p> |

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| <p>1 And as a toxicologist, when you do that, that</p> <p>2 affects the conclusion that you can draw</p> <p>3 about a body of literature.</p> <p>4 Q. Okay. You do understand that</p> <p>5 there is testing data available about the</p> <p>6 percentages of the constituent components</p> <p>7 with respect to heavy metals, et cetera, that</p> <p>8 have been in Johnson's baby powder over time,</p> <p>9 correct?</p> <p>10 A. There is some information.</p> <p>11 Unfortunately, the information is not</p> <p>12 complete as to every lot or every sample, as</p> <p>13 far as what I have seen. And also, there's</p> <p>14 some -- some of the sampling is reported as</p> <p>15 more of a limit versus an actual</p> <p>16 quantification. So it depends upon which --</p> <p>17 which result, study result or document,</p> <p>18 you're looking at.</p> <p>19 There is some there, yes, and</p> <p>20 that's one of the reasons why I identified</p> <p>21 these as part of my risk assessment, because</p> <p>22 I look for a pattern of these metals that are</p> <p>23 known to carry a hazard and whether or not</p> <p>24 these are ones I'm seeing detected time and</p> <p>25 time again.</p> | <p>1 using a word such as an increase -- an</p> <p>2 increased risk.</p> <p>3 Is that a specific number? Am</p> <p>4 I telling you that it's increased by two</p> <p>5 times or four times or six times? No. The</p> <p>6 data available did not allow us to do that,</p> <p>7 with the exception of the epidemiological</p> <p>8 data. And the epidemiological data can show</p> <p>9 you that in that piece of evidence there</p> <p>10 appears to be a 30 percent increased risk</p> <p>11 above background.</p> <p>12 Q. Did you make an attempt to</p> <p>13 quantify the risk with the data that you had</p> <p>14 available to you with respect to the final</p> <p>15 consumer product?</p> <p>16 A. I could not, based on the data</p> <p>17 I had, because I didn't have a</p> <p>18 well-controlled animal study to be able to</p> <p>19 pull that out that way.</p> <p>20 Instead, what I -- in this type</p> <p>21 of weight of the evidence, you look at what</p> <p>22 you might be able to quantify based on the</p> <p>23 human data. And certainly the human data</p> <p>24 showing the statistically significant</p> <p>25 consistent findings across studies for that</p> |
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| <p>1 Q. But you made no attempt to</p> <p>2 quantify the risk with respect to any of</p> <p>3 those components or use that data in any way,</p> <p>4 correct?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: No, I used</p> <p>7 that -- that data as part of -- my</p> <p>8 risk assessment as part of my hazard</p> <p>9 assessment, absolutely. It's part of</p> <p>10 the hazard assessment.</p> <p>11 But as far as quantifying them</p> <p>12 individually, no. I am quantifying</p> <p>13 the risk and looking at the risk of</p> <p>14 the entire product, not of just one</p> <p>15 individual component of the product.</p> <p>16 QUESTIONS BY MS. BRANSCOME:</p> <p>17 Q. Well, we already discussed</p> <p>18 you're not quantifying the risk with respect</p> <p>19 to the entire product, correct?</p> <p>20 A. Well, I'm quantifying it in</p> <p>21 terms of an increase above background, which</p> <p>22 I'm not giving you a -- I told you I wasn't</p> <p>23 giving you a cancer potency factor. That is</p> <p>24 true. That I am not doing.</p> <p>25 But I am quantifying it by</p> | <p>1 30 percent increased risk, that is part of my</p> <p>2 overall weight of the evidence for me making</p> <p>3 the statement the risk is increased.</p> <p>4 But you'll notice I don't say</p> <p>5 increased risk of 30 percent, because I don't</p> <p>6 believe that I can state that with certainty</p> <p>7 in the way I do a risk assessment. But</p> <p>8 certainly as any one individual -- any one</p> <p>9 individual piece of evidence or any one body,</p> <p>10 like the epi data, others have made -- other</p> <p>11 bodies who have looked at the -- talked about</p> <p>12 the consistency of the increased risk signal</p> <p>13 in the epi studies as being in the range of</p> <p>14 30 percent.</p> <p>15 Q. Okay. But you would agree that</p> <p>16 based on the methodology that you applied in</p> <p>17 this case, you could not say to a reasonable</p> <p>18 degree of scientific certainty that there is</p> <p>19 an increased risk of, for example, 30 percent</p> <p>20 with respect to use of Johnson's baby powder</p> <p>21 and ovarian cancer, correct?</p> <p>22 MR. MEADOWS: Objection.</p> <p>23 THE WITNESS: I have not done</p> <p>24 that. And I'm not saying that</p> <p>25 somebody else couldn't do that. I</p> |

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|---|---|
| <p>1 have not -- I have not chosen to do 2 that based on my evaluation of the 3 data. 4 QUESTIONS BY MS. BRANSCOME: 5 Q. And the same would be true if I 6 asked that question and substituted any 7 particular number, a 10 percent increased 8 risk, a 20 percent increased risk, correct? 9 MR. MEADOWS: Objection. 10 THE WITNESS: I haven't given a 11 specific number in my final opinions, 12 that is true. 13 QUESTIONS BY MS. BRANSCOME: 14 Q. Okay. 15 A. I've tried to explain to you 16 what evidence I do think is there, however. 17 Q. Now, we've talked about 18 different types of talc that might have 19 different constituent components, but you 20 also look at exposure to talc in an 21 occupational setting. 22 Do you recall that? 23 A. Some of the studies that I've 24 relied upon, yes, some of them were 25 occupational.</p> | <p>1 Q. Is it your opinion as you sit 2 here today that someone could develop ovarian 3 cancer through -- exclusively through the 4 inhalation of Johnson's baby powder? 5 MS. PARFITT: Objection. 6 THE WITNESS: I haven't formed 7 that opinion at this point in time. 8 QUESTIONS BY MS. BRANSCOME: 9 Q. Have you done any analysis or 10 can you point me to any analysis in your 11 report that makes a comparison of the 12 exposure levels that might be seen in an 13 occupational setting to what would be seen by 14 a consumer? 15 A. Are you asking me for a piece 16 of evidence that does that comparison, or is 17 there evidence that allows you to do that 18 comparison? 19 Q. Have you cited or discussed any 20 of the evidence or done an analysis in any 21 way that would compare exposure levels in an 22 occupational setting to what you would 23 anticipate a consumer using Johnson's baby 24 powder might be exposed to? 25 A. I don't think I did it as a</p> |
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| <p>1 Q. Okay. And you understand that 2 in an occupational setting, you would agree 3 that the exposure, particularly via 4 inhalation, would be much higher than it 5 would be through the use of a consumer 6 product, correct? 7 A. It depends on the occupation, 8 but, yes. For example, I would agree a miner 9 would be expected to have that, but there are 10 certain, quote/unquote, occupational studies 11 where the exposure levels that -- for 12 example, there are -- I believe there's at 13 least one study that looked at application of 14 talc powders in -- maybe in a material, 15 coating materials in a factory. Those kinds 16 of studies would be different than a mining 17 study. 18 But, certainly, yes, I 19 understand that occupational studies, the 20 inhalation exposure is the pathway that would 21 be predominant versus in the consumer body 22 powder use, I'm talking about the predominant 23 exposure pathway in my opinion is going to be 24 through perineal use, even though inhalation 25 exposure can occur.</p> | <p>1 separate analysis, but as part of my analysis 2 I considered evidence that showed -- provided 3 me with such data. So, for example, if you 4 want, I can point you to a -- I have an 5 inhalation paragraph, I think. 6 Let me look for it real quick. 7 See if I can find it quickly for you. I 8 don't want to waste your time. 9 Q. Sure. 10 A. So there's -- I don't see it 11 cited here, but there's at least one document 12 I reviewed where the company themselves made 13 a comparison, and I have seen that, of 14 inhalation exposure to talc suspended in air 15 with diapering. Dr. Longo has done a 16 measurement of exposure in air with perineal 17 application of talc. So I'm aware of those 18 studies. 19 And then I certainly am aware 20 of the fact that those numbers are different, 21 or smaller, than many of the numbers I see 22 reported in some of the occupational studies. 23 But I can't say that's true for all. 24 I would certainly, though, say 25 that if you're just talking inhalation, I</p> |

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| <p>1 certainly would expect a miner or a miller to</p> <p>2 have a greater potential for inhalation</p> <p>3 exposure than routine use of the consumer</p> <p>4 product, with the exception of the studies --</p> <p>5 the reports of large amounts of exposure in</p> <p>6 children where the inhalation -- where they</p> <p>7 were inhaling large amounts of powder.</p> <p>8 And so that's a different</p> <p>9 story. That's sort of an acute overdose</p> <p>10 exposure, I guess, versus the typical daily</p> <p>11 exposure through occupational or consumer</p> <p>12 use.</p> <p>13 Q. And that raises an interesting</p> <p>14 question. You discuss health hazards</p> <p>15 associated with talc being known, and in some</p> <p>16 cases deaths had been reported.</p> <p>17 You're aware that those relate</p> <p>18 to asphyxiation deaths, correct?</p> <p>19 A. Or long-term injury to lungs.</p> <p>20 Maybe not an immediate asphyxiation, but lung</p> <p>21 damage produced by large amounts -- some of</p> <p>22 the children would go to the hospital and be</p> <p>23 sick for a while and then die. So they</p> <p>24 didn't asphyxiate immediately, right? But</p> <p>25 some of them did. You're exactly right.</p> | <p>1 QUESTIONS BY MS. BRANSCOME:</p> <p>2 Q. Okay. Now, you would agree</p> <p>3 that -- so let's set aside inhalation.</p> <p>4 You agree that for talc -- for</p> <p>5 Johnson's baby powder or another one of</p> <p>6 Johnson & Johnson's consumer talc products to</p> <p>7 reach an individual's ovaries, it must pass</p> <p>8 from the perineum, through the vagina and the</p> <p>9 cervical canal, move across the uterus -- and</p> <p>10 again, it's the ciliary motion of the</p> <p>11 fallopian tubes -- cross the peritoneal space</p> <p>12 between the fimbriae and ovaries, escape</p> <p>13 phagocytosis in the peritoneal space, and</p> <p>14 then attach to the surface of the ovaries,</p> <p>15 correct?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 MR. MEADOWS: Okay.</p> <p>18 THE WITNESS: If the issue is</p> <p>19 attaching to the surface, yes.</p> <p>20 There's also some information</p> <p>21 indicates the site of attack may be</p> <p>22 actually at the fallopian tube exit to</p> <p>23 the peritoneum. But, yes, that's</p> <p>24 correct, there's been some discussion</p> <p>25 in the literature on ovarian cancer</p> |
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| <p>1 Both of those things occur, and</p> <p>2 I address that also in my warning section</p> <p>3 about the fact that that warning didn't --</p> <p>4 was not put on the product for a long period</p> <p>5 of time even though those types of reports</p> <p>6 were coming in early.</p> <p>7 Q. You would agree that that is a</p> <p>8 completely different biologic mechanism than</p> <p>9 what you are proposing the biological</p> <p>10 mechanism is for ovarian cancer to develop</p> <p>11 with respect to talc use, correct?</p> <p>12 MR. MEADOWS: Objection.</p> <p>13 THE WITNESS: I would agree</p> <p>14 that it's an acute response versus</p> <p>15 chronic, yes, that I agree with.</p> <p>16 It's not entirely different in</p> <p>17 some cases because some of the tissue</p> <p>18 reactions you saw were indicative of</p> <p>19 irritation when some of the lung</p> <p>20 samples were looked at. But</p> <p>21 certainly, yes, that's acute exposure</p> <p>22 versus chronic exposure, and I'm</p> <p>23 focusing on ovarian cancer on chronic</p> <p>24 exposure scenarios.</p> <p>25</p> | <p>1 about whether the tumors are arising</p> <p>2 in the tubes versus the ovaries.</p> <p>3 But I would agree, I think</p> <p>4 both -- I think both of those</p> <p>5 things -- those things -- there is a</p> <p>6 passage that has to happen, regardless</p> <p>7 of whether the end point is at the</p> <p>8 fallopian tube or at the ovary.</p> <p>9 QUESTIONS BY MS. BRANSCOME:</p> <p>10 Q. Okay. Is it your view that the</p> <p>11 consensus has been reached that ovarian</p> <p>12 cancer can be caused by talc landing in the</p> <p>13 fallopian tubes?</p> <p>14 A. I haven't formed that opinion,</p> <p>15 though I do believe this will be discussed by</p> <p>16 some of the other experts.</p> <p>17 Q. Okay. Have you personally</p> <p>18 conducted any tests or experiments to confirm</p> <p>19 the theory that talc migrates from</p> <p>20 application at the perineum to the ovaries?</p> <p>21 A. If by that you mean something</p> <p>22 where I performed a laboratory test myself,</p> <p>23 no, I have not done that.</p> <p>24 Q. As a toxicologist, are you</p> <p>25 capable of doing that?</p> |

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| <p>1 A. Yes, I believe if asked I 2 could -- I could attempt to design something 3 to look at that issue. 4 Q. Okay. 5 A. But I would argue that I think 6 it doesn't make a lot of sense to revisit 7 based upon what we already know from the 8 scientific literature and the review papers 9 from the gynecological community. I believe 10 it's -- it's understood that it can migrate. 11 Q. In your opinion, has an animal 12 model been successfully developed that would 13 allow the testing of talc migration in humans 14 from the perineum to the ovaries? 15 A. I think I tell that you in my 16 report. I believe that the human data is the 17 relevant data to look at this issue. 18 So it would be very difficult 19 to design a study to do this based on the 20 typical laboratory species that are used in 21 toxicology testing. Even -- even the monkeys 22 have issues, and the biggest issues with 23 monkeys is the ethicality of using a monkey 24 to settle -- to address a question that I 25 believe is settled within the gynecological</p> | <p>1 And then on top of that, you 2 have the review articles that talk about 3 migration of particles in the female 4 reproductive tract and are describing it as 5 an event that is known to occur. So it's 6 those things weighed together. 7 But certainly routine could be 8 supported by the observations where the 9 majority of the patients in the studies were 10 showing movement of inert particles. 11 Q. Is it your opinion that every 12 perineal application of cosmetic talc powder 13 results in talc being deposited on the 14 ovaries? 15 A. I have not formed that opinion, 16 no. 17 Q. Have you formed an opinion as 18 to with what frequency -- so let's say 19 someone uses a cosmetic talc on a perineal 20 application ten times. Out of those ten 21 times, have you formed an opinion as to how 22 many of those instances would talc deposit on 23 the ovaries? 24 MS. PARFITT: Objection. 25 THE WITNESS: I haven't formed</p> |
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| <p>1 and scientific community. 2 Q. Now, you state in your report 3 that talc that's applied through perineal 4 use -- I believe the term you use -- 5 routinely migrates to the ovaries. 6 Is that your opinion? 7 A. Are you reading from my report? 8 MR. MEADOWS: To the extent 9 that question is still lingering, I 10 object to it. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. On paragraph 43 on page 29. 13 A. So I think as I've stated it, 14 the studies that I have reviewed demonstrate 15 that inert particles routinely move from the 16 lower female reproductive tract up into 17 fallopian tubes and towards the ovaries. 18 Q. What do you mean by routinely? 19 A. It's the percentages of 20 movement that are reported in the patients. 21 In other words, if you look at some of the 22 individual studies -- if you want we can pull 23 them out, but, you know, eight of ten 24 patients, nine of ten patients, all the 25 patients showed movement of the particles.</p> | <p>1 an opinion in that particular way, no. 2 I think what I've -- I've tried to 3 describe to you in my report is that I 4 believe it is known that inert 5 particles have the ability to migrate. 6 And based on that, I form the opinion 7 that it's my opinion to a reasonable 8 degree of scientific certainty, which 9 would be a more likely than not 10 standard, that particles of talc would 11 be migrating when women are using them 12 perineally. But I haven't told you 13 that it has to be a specific number, 14 no. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. Have you done any analysis to 17 establish over a lifetime use of cosmetic 18 talc where the app -- the perineal 19 application, with what frequency during a 20 lifetime the talc may have been deposited on 21 that individual's ovaries? 22 A. So I certainly looked for 23 information to allow me to assess that, but 24 unfortunately those kinds of studies would be 25 unethical to do. Because that would be a</p> |

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| <p>1 matter of sampling women during -- using them</p> <p>2 and then taking biopsies, and that's</p> <p>3 something that would be difficult to do. I</p> <p>4 would say impossible to get approval to do</p> <p>5 under human testing guidelines.</p> <p>6 Q. Okay. So it's your opinion</p> <p>7 that it is possible for talc that is applied</p> <p>8 through a perineal application to reach the</p> <p>9 ovaries, but you cannot say with what</p> <p>10 frequency that occurs?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 Misstates her testimony.</p> <p>13 THE WITNESS: That's not --</p> <p>14 what I'm telling you is, I think it --</p> <p>15 that to a reasonable degree of</p> <p>16 scientific certainty that it migrates,</p> <p>17 and that would be the standard of more</p> <p>18 likely than not. I think it's more</p> <p>19 likely than not that the talc is</p> <p>20 reaching the ovaries when people are</p> <p>21 using it perineally.</p> <p>22 I did form the opinion -- and</p> <p>23 I've talked about this at trial and</p> <p>24 yesterday. I have formed the opinion</p> <p>25 that this is a issue of chronic or --</p> | <p>1 MS. BRANSCOME: Okay. Can we</p> <p>2 just go off the record for a second?</p> <p>3 VIDEOGRAPHER: We are going off</p> <p>4 the record at 12:23 p.m.</p> <p>5 (Off the record at 12:23 p.m.)</p> <p>6 VIDEOGRAPHER: We are back on</p> <p>7 the record at 12:24 p.m.</p> <p>8 QUESTIONS BY MS. BRANSCOME:</p> <p>9 Q. As you sit here today, how</p> <p>10 would you characterize the biological</p> <p>11 mechanism by which you claim Johnson's baby</p> <p>12 powder, their other cosmetic talc products,</p> <p>13 present a risk of ovarian cancer?</p> <p>14 A. So I outline this for you in</p> <p>15 the MDL report. I think I have a section</p> <p>16 on -- let's see if I can -- you want me to</p> <p>17 tell you where or...</p> <p>18 So paragraph 65, I think I set</p> <p>19 out part of this argument or part of this.</p> <p>20 And then also in paragraph -- I believe in</p> <p>21 67.</p> <p>22 Q. All right. Well, let me take a</p> <p>23 step back.</p> <p>24 Is it your opinion that the</p> <p>25 biological mechanism by which talc, cosmetic</p> |
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| <p>1 or use of the products. In other</p> <p>2 words, people aren't just using it</p> <p>3 once, but people are using it -- you</p> <p>4 can use the word "routinely," as a</p> <p>5 habit, in their daily life perineally.</p> <p>6 And that would be consistent with the</p> <p>7 studies that have been done that have</p> <p>8 looked at the issue of dose response.</p> <p>9 And I discuss that in my</p> <p>10 report, too.</p> <p>11 QUESTIONS BY MS. BRANSCOME:</p> <p>12 Q. Okay. But you have not made an</p> <p>13 attempt to quantify, nor have you seen it in</p> <p>14 the literature, the overall dose of talc that</p> <p>15 someone might be exposed to in terms of</p> <p>16 contact with the ovaries throughout their</p> <p>17 lifetime, chronic use of cosmetic talc?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: Those -- that's</p> <p>20 the kinds of studies that have not</p> <p>21 been done and I believe could not be</p> <p>22 done based upon ethics of human</p> <p>23 testing. But certainly I -- that --</p> <p>24 that data is not available that I'm</p> <p>25 aware of.</p> | <p>1 talc, can in your view cause ovarian cancer,</p> <p>2 is that something that has been definitively</p> <p>3 established?</p> <p>4 A. What do you mean by</p> <p>5 definitively? I mean, I think -- I believe</p> <p>6 more likely than not that -- so I believe I</p> <p>7 have reached a conclusion that I think what</p> <p>8 the most likely biologically plausible</p> <p>9 mechanism, but maybe you're ask -- meaning</p> <p>10 something else.</p> <p>11 Q. Okay. Well, let's start with</p> <p>12 specifically you discuss a number of</p> <p>13 different potential mechanisms in your</p> <p>14 report. So if you believe you have reached</p> <p>15 an opinion more likely than not about the</p> <p>16 specific biological mechanism by which</p> <p>17 cosmetic talc and specifically Johnson &</p> <p>18 Johnson's products can cause ovarian cancer,</p> <p>19 can you describe that for me?</p> <p>20 A. So it's a chronic inflammatory</p> <p>21 process, and so -- but like all compounds,</p> <p>22 constituents, even drugs that we look at, we</p> <p>23 don't know each individual step within the</p> <p>24 molecular mechanism.</p> <p>25 Instead, what we know is that</p> |

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| <p>1 there are certain components to the process</p> <p>2 of cancer that are consistent with the</p> <p>3 effects produced by talc, and we know that</p> <p>4 talc can produce a chronic inflammatory</p> <p>5 process.</p> <p>6 And so that's why I was</p> <p>7 pointing you to the paragraph 65 and I think</p> <p>8 67.</p> <p>9 Q. Is it your opinion that</p> <p>10 consensus has been reached in the scientific</p> <p>11 community that cosmetic talc can cause</p> <p>12 ovarian cancer through a chronic inflammatory</p> <p>13 response?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: I don't know that</p> <p>16 that's exactly the opinion I've</p> <p>17 formed.</p> <p>18 Would you like me to -- I could</p> <p>19 restate what I believe, but I don't</p> <p>20 think that's exactly how I would state</p> <p>21 it, no.</p> <p>22 QUESTIONS BY MS. BRANSCOME:</p> <p>23 Q. Okay. So then yes or no: Has</p> <p>24 consensus been reached in the scientific</p> <p>25 community that cosmetic talc can cause</p> | <p>1 discuss those issues.</p> <p>2 I think it's consistent with --</p> <p>3 I don't know if the ACOG statement goes that</p> <p>4 far on mechanism, but it does talk about</p> <p>5 ovarian cancer. That's a recent statement.</p> <p>6 And I believe it's consistent</p> <p>7 with some of the -- I believe my opinions are</p> <p>8 consistent with some of the opinions reached</p> <p>9 by others in science, but that's the only way</p> <p>10 I can answer that for you.</p> <p>11 Q. Okay. Because you have not,</p> <p>12 one way or the other, done an evaluation of</p> <p>13 whether or not chronic inflammatory process</p> <p>14 is a biological mechanism on which the</p> <p>15 scientific community has reached general</p> <p>16 consensus with respect to the causation of</p> <p>17 ovarian cancer; is that correct?</p> <p>18 MR. MEADOWS: Objection.</p> <p>19 THE WITNESS: I can't tell you</p> <p>20 that -- I can't tell you that every</p> <p>21 body that's looked at it, but I have</p> <p>22 tried to point you to evidence that I</p> <p>23 believe is consistent with that.</p> <p>24 For example, the IARC would be</p> <p>25 a good example of consensus on</p> |
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| <p>1 ovarian cancer through a chronic inflammatory</p> <p>2 process?</p> <p>3 A. I don't believe I formed the</p> <p>4 opinion either way, that it's yes or no,</p> <p>5 because I haven't tried to -- I haven't tried</p> <p>6 to form the opinion about what the -- in</p> <p>7 other words, I haven't -- I can't say for</p> <p>8 every scientist out there.</p> <p>9 I certainly can tell you what I</p> <p>10 believe based on what the consensus of</p> <p>11 science says about mechanisms underlying</p> <p>12 cancer and the consistency of those</p> <p>13 mechanisms with talc, and then I have an</p> <p>14 opinion about what I believe that information</p> <p>15 says.</p> <p>16 I do believe my opinions,</p> <p>17 however, are consistent with some consensus</p> <p>18 statements, such as the issue on the</p> <p>19 mechanism is consistent with consensus</p> <p>20 opinion reached by IARC, where they discuss</p> <p>21 the inflammatory process as an underlying</p> <p>22 biologically plausible mechanism that can</p> <p>23 lead to ovarian cancer.</p> <p>24 I think it's consistent with</p> <p>25 the Canadian risk assessment where they</p> | <p>1 biologic mechanism because they have a</p> <p>2 whole part of their assessment of</p> <p>3 non-asbestiform talc and perineal</p> <p>4 cancer -- of perineal use and ovarian</p> <p>5 cancer that discusses mechanism. And</p> <p>6 that is consistent with what I have</p> <p>7 said. So there is a consensus</p> <p>8 opinion.</p> <p>9 But I guess what I'm saying to</p> <p>10 you is I can't tell you that all --</p> <p>11 all people who have put statements</p> <p>12 have come to that exact opinion. But</p> <p>13 there aren't that many places out</p> <p>14 there that are addressing that issue</p> <p>15 as far as the consensus on a</p> <p>16 mechanism. There's more statements</p> <p>17 about the relationship between ovarian</p> <p>18 cancer and talc use than there are</p> <p>19 drilling down to what the mechanism</p> <p>20 must be.</p> <p>21 QUESTIONS BY MS. BRANSCOME:</p> <p>22 Q. Okay.</p> <p>23 A. So that's the issue. It's a</p> <p>24 little -- it's a little hard to answer that</p> <p>25 yes or no because of that.</p> |

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| <p>1 Q. Okay. When we talk about the 2 idea of biologic -- a biologically plausible 3 mechanism, what is your understanding of the 4 term "plausible" in that expression? 5 A. When I use the word 6 "biologically plausible mechanism" or 7 "biologic plausibility," I'm using it 8 consistent with what Bradford Hill uses, 9 that's it's the idea that the evidence that 10 available makes -- the evidence that 11 available supports a pathway where you can go 12 to exposure to response. 13 So in other words, there's a -- 14 the biological information is consistent with 15 how we know cancer can develop. That's the 16 response we're looking at. And the exposure 17 we're looking at is known to produce those 18 kind of biological events. 19 So as a result, based upon 20 knowing that there's a consistency between 21 the data that we have on the -- on the 22 exposure and the data that we have on the way 23 cancer can occur, those things -- those 24 things align. So that makes it biologically 25 plausible that that could occur.</p> | <p>1 are known to be able to produce, 2 specifically, ovarian cancer. 3 QUESTIONS BY MS. BRANSCOME: 4 Q. Is it your opinion that IARC, 5 for example, has concluded that the 6 biological mechanism by which talc may cause 7 ovarian cancer is chronic inflammation? 8 MS. PARFITT: Objection. 9 THE WITNESS: I don't know that 10 they have used -- they've described it 11 quite that way, but they do describe 12 what they believe is the biologically 13 plausible mechanism. Because they do 14 organize and use within the 15 definitions of how they describe some 16 things that are consistent with what 17 Bradford Hill uses. 18 QUESTIONS BY MS. BRANSCOME: 19 Q. Okay. And obviously you're 20 familiar with the IARC evaluation of talc 21 with respect to the possibility of causing 22 ovarian cancer, correct? 23 A. Yeah. If you mean the recent 24 one, yes, the most recent assessment. 25 Q. Yes.</p> |
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| <p>1 Q. But you would agree that 2 biological plausibility suggests that it is a 3 plausible explanation, but it may not have 4 been established as the definitive pathway by 5 which a disease is caused, correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: Well, I would 8 agree that in the discussion of 9 biologic plausibility in the Bradford 10 Hill paper that is true. But if you 11 look at people's discussion of the use 12 of -- I want to say "biological 13 mechanism" rather than the word 14 "biologic plausibility," because 15 really as a toxicologist I'm trying to 16 understand whether there's a biologic 17 mechanism that makes sense. Those are 18 words I like to use. Does it make 19 sense that this exposure could lead to 20 this response. 21 And that involved looking at 22 the mechanistic data or the data on 23 the way toxic responses are produced 24 by talc, and whether or not they align 25 with the types of toxic insults that</p> | <p>1 And that IARC has in fact 2 classified cosmetic talc not containing 3 asbestos as possibly carcinogenic to humans, 4 correct? 5 A. It's a possible human 6 carcinogen 2B, that's correct. 7 Q. Okay. And if a product is 8 listed in the 2B category, does that 9 necessarily mean the product, in your view, 10 is carcinogenic? 11 A. Not always, because that comes 12 down to an assessment of -- then you're 13 putting together a -- a risk assessment that 14 looks at -- looks at -- across the 15 information that you have available. And 16 that may be that -- that the -- the possible 17 is all you can say, or it may be that you 18 believe that the information -- there's 19 enough information there to take it further. 20 Has a possibility -- that's 21 what I said, they do a hazard assessment. 22 They rank things on hazard based on -- on 23 unlikely -- not enough evidence, less -- the 24 possibility, the probability or it's known. 25 Q. In your opinion, is your</p> |

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| <p>1 characterization of the risk of Johnson's 2 baby powder or talcum powder products with 3 respect to ovarian cancer, are you in the MDL 4 characterizing that risk as a higher level of 5 risk than what IARC characterized it, or do 6 you agree with the 2B characterization of 7 possibly carcinogenic? 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: So I'm not IARC, 10 so I don't try to second-guess there. 11 They have reached a conclusion, and I 12 use that as part of my weight of the 13 evidence. So I haven't formed the 14 opinion they're right or wrong. 15 But I have done a different 16 assessment. My assessment, first off, 17 includes more information than IARC 18 had, so as a result, I have formed the 19 conclusion that I believe that it's 20 more likely than not that exposure 21 to -- perineal exposure to talc body 22 powders increases the risk of ovarian 23 cancer in women who use that product. 24 And I will put the caveat this 25 has to be chronic use or repeated use,</p> | <p>1 opinion. 2 Q. Is there a threshold of the use 3 of Johnson & Johnson's talcum powder products 4 below which there is no increased risk, in 5 your opinion, of ovarian cancer? 6 A. We have not identified that 7 threshold. That's what's missing within 8 the -- the literature that exists today. So 9 I can't tell you whether or not with only a 10 thousand applications over a lifetime that 11 is -- is not enough for every individual or 12 not, but certainly I do believe that the -- 13 that the exposure has to be habit, routine, 14 chronic, something that is done maybe not on 15 a daily basis but on a routine basis in a 16 woman's life. 17 So that is consistent, I think, 18 with the literature. 19 MS. BRANSCOME: Okay. We can 20 go off the record. 21 VIDEOGRAPHER: We are going off 22 the record at 12:36 p.m. 23 (Off the record at 12:36 p.m.) 24 VIDEOGRAPHER: We are back on 25 the record at 1:35 p.m.</p> |
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| <p>1 because I've gone -- I've said that 2 many times. 3 So that -- that is my opinion. 4 So that's a different statement and a 5 different assessment than what IARC 6 does. 7 But -- so I don't disagree with 8 their possible -- I weigh that, but I 9 believe the evidence for the risk 10 assessment shows me that it's more 11 likely than not that this -- this 12 exposure will increase the risk above 13 a background risk for women who are 14 using this product. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. And how do you define chronic 17 or repeated use? 18 A. Well, that is variable within 19 the literature. For me, chronic is 20 exposure -- if as a toxicologist, I would 21 typically say chronic use is years of use. 22 It doesn't have to be daily, but it would be 23 years. That's the most common description 24 you see in toxicology, so I would say that's 25 fair. That's a fair assessment of my</p> | <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Good afternoon again, 3 Dr. Plunkett. 4 A. Good afternoon. 5 Q. I want to talk a little bit 6 about the Health Canada assessment. 7 We talked about this before, 8 but this is something that you reviewed after 9 you completed your report which has been 10 marked as Exhibit 4, correct? 11 A. Yes, and I wanted to tell you, 12 I did not bring all those documents printed. 13 I apologize. So there is a separate Health 14 Canada draft risk assessment that I didn't 15 print. 16 Q. Okay. So when you're referring 17 to the Health Canada analysis, what document 18 are you specifically referring to? 19 A. So I'm referring to the -- the 20 combined documents, but there are times when 21 you've asked me questions that I've been 22 referring -- and I tried to say, I believe, 23 Taher. 24 But, yes, some of the questions 25 you asked me when I said Health Canada, I was</p> |

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| <p>1 talking about the combined documents, which</p> <p>2 would include their -- I guess it's called a</p> <p>3 draft risk assessment document, yeah, which</p> <p>4 refers to this document but is a separate --</p> <p>5 is their own separate statement.</p> <p>6 Q. As you sit here today, what is</p> <p>7 your understanding of the current position</p> <p>8 that has been articulated in the collection</p> <p>9 of documents that you refer to as Health</p> <p>10 Canada with respect to any potential</p> <p>11 relationship between cosmetic talc and</p> <p>12 ovarian cancer?</p> <p>13 A. So that's why I did print out</p> <p>14 the small one, because I think it summarized</p> <p>15 it. So here, if you look at this Exhibit 6,</p> <p>16 it makes specific conclusions or draws --</p> <p>17 makes statements. And essentially it talks</p> <p>18 about talc being a possible risk of ovarian</p> <p>19 cancer, but then it gives women specific</p> <p>20 advice about what to do in order to minimize</p> <p>21 exposure to the products, and some of that</p> <p>22 was relevant as well.</p> <p>23 Just one reason I printed it</p> <p>24 out, it has to do with either choosing an</p> <p>25 alternative product or avoiding genital</p> | <p>1 there is a association between those two</p> <p>2 things, the exposure and the response, which</p> <p>3 is more than a possible association, if you</p> <p>4 want to use those words.</p> <p>5 But my assessment that I've</p> <p>6 done is not exactly the same, for example, as</p> <p>7 IARC does, which is more of just a hazard</p> <p>8 assessment.</p> <p>9 Q. Right.</p> <p>10 So I'm focusing my questions</p> <p>11 now on your risk assessment as compared to</p> <p>12 the documents that you've supplied us with</p> <p>13 with respect to Health Canada. And if I</p> <p>14 understand it correctly, are you stating that</p> <p>15 your opinion with respect to the relationship</p> <p>16 between cosmetic talc and ovarian cancer, you</p> <p>17 believe that it is an association that is</p> <p>18 stronger than a possible risk; is that</p> <p>19 correct?</p> <p>20 A. Well, I don't say it's a</p> <p>21 possible risk; I say there is an increased</p> <p>22 risk. So I think it's a different statement,</p> <p>23 yes, absolutely.</p> <p>24 Of course, I'm not Health</p> <p>25 Canada, so, you know, they have a framework</p> |
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| <p>1 exposure to talc.</p> <p>2 And let me see the exact words</p> <p>3 that they use, but --</p> <p>4 Q. Before you do that, do you</p> <p>5 agree with the characterization that cosmetic</p> <p>6 talc presents a possible risk of ovarian</p> <p>7 cancer?</p> <p>8 A. No, I don't think that's my</p> <p>9 opinion. I think my opinion is stronger than</p> <p>10 that.</p> <p>11 But are you talking about my</p> <p>12 causation analysis opinion or just my risk</p> <p>13 assessment opinion?</p> <p>14 Q. I'm asking about any opinion</p> <p>15 you intend to offer in the MDL.</p> <p>16 A. Okay. So I will not be giving</p> <p>17 the causation analysis opinion, so that -- I</p> <p>18 will take that off the table.</p> <p>19 So I think my opinion is a</p> <p>20 little stronger because I say that the</p> <p>21 exposure to the perineal -- the talc by</p> <p>22 perineal application in women increases the</p> <p>23 risk. So I'm not saying it's a possible</p> <p>24 risk. I'm actually -- I believe that it</p> <p>25 increases the risk. And I do believe that</p> | <p>1 upon which they make decisions, and I'm doing</p> <p>2 an analysis based on what I have done. And</p> <p>3 so it's not exactly the same, although some</p> <p>4 of the same documents and information is</p> <p>5 weighed within -- and then that's when you</p> <p>6 have the issue of what Health Canada does</p> <p>7 versus what they rely upon.</p> <p>8 But this Taher risk assessment</p> <p>9 is just one piece of information that Health</p> <p>10 Canada has weighed in their assessment if you</p> <p>11 read their -- their draft risk assessment.</p> <p>12 Q. So the question I have about</p> <p>13 the Taher risk assessment, earlier you were</p> <p>14 referring to the fact that you have only seen</p> <p>15 a quantitative assessment of the weight of</p> <p>16 particular components of scientific evidence</p> <p>17 in evaluating epidemiological studies; is</p> <p>18 that correct?</p> <p>19 A. So that's what I typically see,</p> <p>20 yes. And I don't know that -- I've never</p> <p>21 seen it. But the typical approach would be</p> <p>22 to use it there as opposed to using it in the</p> <p>23 context of a human health risk assessment</p> <p>24 based on animal in vitro data.</p> <p>25 Q. All right. Are you familiar</p> |

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| <p>1 with something called the Klimisch scoring 2 system? 3 A. I don't know if I am now. 4 You'll need to show me what it is you're 5 referring to. The name doesn't ring a bell, 6 no. 7 Q. Okay. So it's not something 8 that you've used in the past? 9 A. No, not that I recall using. 10 Q. All right. 11 A. Unless it has another name, and 12 that's why I'm asking you. 13 Q. All right. So if you have 14 actually -- it's the document in front of you 15 that we've already marked as Deposition 16 Exhibit 5, I believe. 17 A. Yes. 18 Q. And that is the Taher study 19 that we were discussing and is cited by the 20 Health Canada risk assessment. 21 If you turn to page 5 -- well, 22 actually beginning on page 4, do you see 23 there is a section entitled "Literature 24 Search and Identification of Relevant 25 Nonhuman Studies"?</p> | <p>1 So, yes, if they stated they've 2 done -- we'd have to pull the supplementary 3 materials out, but I recall them doing 4 scoring based on epi studies but not on 5 the -- all of the animal studies that they 6 talk about. But we can pull it out and look. 7 I could be wrong. 8 Q. Okay. Did you review the 9 supplementary material 7, 8 and 9? 10 A. Yes, I did, and we'd have to 11 pull them out because I don't recall the 12 details. 13 Q. All right. We may take a look 14 at those in a minute. 15 It talks about them classifying 16 the animal and in vitro studies into four 17 categories of reliability. 18 Do you see that? 19 A. Yes. 20 Q. So did you make any attempt, 21 when you were reviewing the various studies 22 in reaching your opinion about the potential 23 risk of talc in causing ovarian cancer, did 24 you make any attempt to separate out the 25 different pieces of evidence into categories</p> |
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| <p>1 Do you see that? 2 A. Yes. 3 Q. And this is related to an 4 analysis that these authors performed on 5 potentially relevant animal and in vitro 6 studies, correct? 7 A. Yes, that is true. 8 Q. All right. And it states here 9 that "all retrieved studies were examined for 10 relevance, reliability and overall quality 11 using the Klimisch scoring system." 12 Do you see that? 13 A. Yes, I do see that. So I have 14 seen that before. I just didn't -- I didn't 15 recall it. 16 Q. Okay. And so would you agree 17 that it is possible and in fact has been done 18 in a study that you rely on to apply a 19 quantitative scoring system to animal and in 20 vitro studies, particularly in the context of 21 looking at the relationship between talc and 22 ovarian cancer? 23 A. Well, I didn't say it was 24 impossible. I said I don't believe it's 25 routine based on my experience.</p> | <p>1 of reliability like the authors of this paper 2 have done? 3 A. I didn't do it exactly the way 4 they did it, but I certainly do do that as 5 part of my screening. 6 I told you one of the 7 characteristics or one of the assessments I 8 make is whether I believe the data is 9 reliable data that I can -- that I can use in 10 a weight of the evidence. So I make a -- and 11 when I talk about reliability, I'm talking 12 then about things such as I mentioned, peer 13 review, whether or not there is statistical 14 analysis, whether or not the study is 15 designed in a way that's consistent with 16 general principles of toxicology, control 17 groups or not control groups. 18 Those kinds of things I do -- I 19 do consider when I am assessing the use of a 20 study or not. 21 Q. Is it your testimony here today 22 that contained within your report that's 23 marked as Exhibit 4, I could find 24 categorization of reliability of each of the 25 pieces of scientific literature that you have</p> |

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| <p>1 included in your weight of the evidence 2 analysis? Is that your testimony today? 3 A. No, that's not what I'm telling 4 you, no. 5 Q. Okay. So you would agree that 6 you did not -- first of all, did you develop 7 categories of reliability in which you 8 separated the particular scientific studies 9 into as part of your weight of the evidence 10 analysis? 11 A. I do look at -- I do categorize 12 studies based upon my assessment of their 13 reliability and their ability to be used to 14 answer the question I'm asking, but I -- I 15 already told you, I didn't do it the way it's 16 set out here. I didn't have these specific 17 five categories, no. That's not what I did. 18 Q. Okay. Other than the CIR 2013 19 publication, which you have said that you do 20 not find reliable and you assign little 21 weight to it, can you point me to another 22 place in Exhibit 4 where you assign a 23 specific category of weight that you have 24 given to a particular study that you include 25 in your weight of the evidence analysis?</p> | <p>1 reliance list? 2 A. I believe it was, yes. 3 Q. Okay. And so for this one I 4 just want to direct your attention to the 5 conclusion section -- well, let me ask you 6 first: How does this document relate to the 7 collection of documents with respect to 8 Health Canada that you identified as relevant 9 to your opinion? 10 A. It was one of the materials 11 that they rely upon or they cite. That's the 12 reason I pulled it. It was -- I pulled 13 documents that they provided on the website 14 that were cited. 15 Q. Okay. And if you could turn to 16 page 11 of that document, there's a 17 conclusion section. The first sentence of 18 the third paragraph reads, "The given -- 19 given the context-specific nature of each 20 risk assessment and the diversity of tools 21 and criteria applicable, transparent 22 documentation of the specific application of 23 the WOE approach is especially important." 24 Did I read that correctly? 25 A. Yes, you did.</p> |
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| <p>1 A. If what you're asking me is do 2 I make a specific statement next to each 3 study that I discuss about little weight or 4 great weight, no, I don't do that, if that's 5 what you're asking me. 6 Q. Okay. As part of the 7 collection of documents that relate to Health 8 Canada that was provided to us as part of 9 your new reliance list, did you review a 10 document entitled weight of the evidence -- 11 or "Weight of evidence: General principles 12 and current applications of Health Canada"? 13 A. Yes, I've seen that. 14 (Plunkett Exhibit 8 marked for 15 identification.) 16 QUESTIONS BY MS. BRANSCOME: 17 Q. All right. We will mark this 18 as Plunkett Deposition Exhibit Number 8. 19 All right. The document that I 20 just handed you that's marked as Plunkett 21 Deposition Exhibit Number 8, are you familiar 22 with that document, Dr. Plunkett? 23 A. Yep, I've seen this before. 24 Q. Is this listed among the new 25 materials that have been added to your</p> | <p>1 Q. And is your understanding of 2 WOE that it is weight of evidence? 3 A. Yes, that's correct. 4 Q. Do you agree with this 5 statement? 6 A. In a regulatory context, I do 7 believe that that is true, because within the 8 regulatory context when they do the risk 9 assessment, there's a need to understand why 10 decisions are made. So, absolutely, in a 11 regulatory context, I would agree that this 12 kind of transparency is even being adopted by 13 EPA. 14 Q. And is it your opinion then 15 that a different level of transparency is 16 needed for expert testimony in court? 17 A. No, that's not what I'm saying. 18 I'm saying that's a different process. And 19 that's what part of this process is. It's 20 understanding the ability to provide a dialog 21 about what was done. 22 So as a result, this is 23 something that is common to the work that 24 I've done in the past. Even in a 25 nonlitigation context with my regulatory</p> |

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| <p>1 clients, doing a risk assessment doesn't</p> <p>2 necessarily involve the same level of detail</p> <p>3 that a regulatory -- a regulator would apply</p> <p>4 to the transparency of the assessment. Not</p> <p>5 to say that it couldn't be done, but it's</p> <p>6 just -- I would say it's not necessarily</p> <p>7 typical.</p> <p>8 Q. So this specifically refers to</p> <p>9 transparent documentation.</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Would you agree that the report</p> <p>13 that you have produced in the MDL does not</p> <p>14 have documentation of the specific</p> <p>15 application of the weight of evidence</p> <p>16 approach?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 Excuse me, objection. Form.</p> <p>19 THE WITNESS: I disagree to an</p> <p>20 extent because I did attempt to</p> <p>21 provide in my report a description of</p> <p>22 the methods that I used and the</p> <p>23 resources that I've relied upon for a</p> <p>24 discussion of how those methods are</p> <p>25 used.</p> | <p>1 study. In other words, as I discussed many</p> <p>2 times in deposition, when you're talking</p> <p>3 about doing a human health risk assessment,</p> <p>4 there's certain types of data that are most</p> <p>5 relevant. I mean, when they use the word</p> <p>6 "reliable" -- I don't know that many of these</p> <p>7 studies have the same level of reliability as</p> <p>8 far as peer review, but they're -- for</p> <p>9 example, on the issue of migration, it's my</p> <p>10 opinion that the data from the human studies</p> <p>11 is a more reliable or relevant source of</p> <p>12 information. And I've laid out why, because</p> <p>13 of differences in the anatomy, things like</p> <p>14 that, with the data.</p> <p>15 Q. Are you familiar with the term</p> <p>16 "binning exercise"?</p> <p>17 A. Yes, I am. And that is</p> <p>18 certainly something that I have used in other</p> <p>19 aspects of work that I have done.</p> <p>20 Q. Did you do a binning exercise</p> <p>21 in rendering your opinions and what you've</p> <p>22 provided to us in the context of your</p> <p>23 opinions in the MDL?</p> <p>24 A. Yes, that's the exercise I</p> <p>25 start with. I'm binning them into human,</p> |
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| <p>1 And then in addition to that,</p> <p>2 I've attempted to lay out for you in</p> <p>3 my report a discussion of the pieces</p> <p>4 of evidence that I've relied upon,</p> <p>5 including some -- for some of those --</p> <p>6 that's one of the reasons I got so</p> <p>7 detailed in the section on migration</p> <p>8 and providing you an analysis of each</p> <p>9 of the papers that I relied upon and</p> <p>10 what I thought was important within</p> <p>11 them that led to my -- the formation</p> <p>12 of my opinions.</p> <p>13 So I disagree to some extent.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. Okay. Turning back to what</p> <p>16 Taher did in classifying different studies</p> <p>17 into different categories of reliability.</p> <p>18 Have you done that type of analysis in the</p> <p>19 past where you have separated out different</p> <p>20 studies into different categories of weight</p> <p>21 or reliability as part of an overall</p> <p>22 analysis?</p> <p>23 A. Well, I do that every time I do</p> <p>24 a weight of the evidence when I separate into</p> <p>25 categories first based upon the type of</p> | <p>1 animal, mechanistic, in vitro data. That's</p> <p>2 the first bins.</p> <p>3 In fact, in the copper work we</p> <p>4 did, that's what we did. We separated the</p> <p>5 data into in vitro/only mechanistic</p> <p>6 information, animal studies, did we have</p> <p>7 human studies.</p> <p>8 And we also looked at</p> <p>9 studies -- we had a separate bin of exposures</p> <p>10 like I do. I have studies that just address</p> <p>11 the issue of exposure potentially.</p> <p>12 So, yes, it's -- it's</p> <p>13 consistent with doing that. It's --</p> <p>14 essentially binning is just separating the</p> <p>15 information into groups based on what</p> <p>16 questions those -- those data can answer.</p> <p>17 Q. Okay. Have you ever -- do you</p> <p>18 ever separate them into bins based on the</p> <p>19 level of weight that you would give a</p> <p>20 particular study?</p> <p>21 A. I do that when I'm analyzing</p> <p>22 each of the studies within that group or that</p> <p>23 bin. That's what I do. I give them -- in my</p> <p>24 weight -- in my analysis, I weigh those</p> <p>25 studies based upon my judgment on the</p> |

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| <p>1 relevance, the reliability, the power of the</p> <p>2 study, the statistical analysis that's done,</p> <p>3 the inclusion in animal studies, in</p> <p>4 particular, of controls. Those are all parts</p> <p>5 of that analysis that I do. So, yes, I do do</p> <p>6 that.</p> <p>7 And then in -- there have been</p> <p>8 exercises that I've done in the past with</p> <p>9 other individuals where we may have taken a</p> <p>10 yellow sticky note and put down on top of it</p> <p>11 animal data with exposure information, animal</p> <p>12 data without exposure information. That's</p> <p>13 the process that I'm doing when I am looking</p> <p>14 across the data. I'm separating those pieces</p> <p>15 of data into groups and what types of</p> <p>16 questions they can answer.</p> <p>17 So that is consistent with what</p> <p>18 I do when I do a weight of analysis approach</p> <p>19 in the work that I do in both nonlitigation</p> <p>20 and litigation context.</p> <p>21 Q. Okay. But we have no specific</p> <p>22 documentation of the different ratings that</p> <p>23 you gave the various pieces of evidence that</p> <p>24 you included in your weight of the evidence</p> <p>25 analysis, aside from occasional references to</p> | <p>1 inflammation, cause ovarian cancer?</p> <p>2 A. Because it doesn't change the</p> <p>3 phenotype of the cell. It has to -- the --</p> <p>4 and I discuss that. You have to -- you have</p> <p>5 to set up a chronic inflammatory process that</p> <p>6 leads to changes within the cellular</p> <p>7 phenotype to go from a cell that is -- that</p> <p>8 is -- is dividing normally to a cell that</p> <p>9 isn't.</p> <p>10 So it's -- it's the same issue</p> <p>11 that you address even in a study in animals.</p> <p>12 Why do not all animals exposed to -- exposed</p> <p>13 to a chemical develop tumors. It's the idea</p> <p>14 that something has to be initiated beyond the</p> <p>15 exposure or maybe beyond inflammation to lead</p> <p>16 to the series of events.</p> <p>17 And so, yes, it's recognized</p> <p>18 that you can get inflammation, and</p> <p>19 inflammation can go down the road in becoming</p> <p>20 a carcinogenic process, or inflammation can</p> <p>21 no longer -- can stay where it is. It</p> <p>22 doesn't progress beyond just a chronic</p> <p>23 inflammatory process.</p> <p>24 Q. And so if you had a study that</p> <p>25 demonstrated that a particular agent causes</p> |
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| <p>1 giving something less or more weight,</p> <p>2 correct?</p> <p>3 A. Well, I certainly -- I told you</p> <p>4 I have not given numerical values that you're</p> <p>5 asking me, but I've attempted to do that when</p> <p>6 I have described them in groups, when I talk</p> <p>7 about human versus animal versus in vitro.</p> <p>8 Because I've already told you, I believe,</p> <p>9 it's my opinion that certain types of</p> <p>10 information are more informative than others.</p> <p>11 And so the more informative it is, the more</p> <p>12 weight you're giving it in -- obviously in</p> <p>13 your analysis.</p> <p>14 But it is a different exercise</p> <p>15 than what is described here. And here I'm</p> <p>16 pointing to Exhibit 8. And it's a different</p> <p>17 exercise, obviously, than what a regulatory</p> <p>18 body is required to do where they are trying</p> <p>19 to come up with ways to increase the</p> <p>20 transparency when no one can go and actually</p> <p>21 talk to each of the regulators individually</p> <p>22 to understand what their thinking was.</p> <p>23 Q. Okay. Returning to biological</p> <p>24 mechanism for a minute, why doesn't</p> <p>25 inflammation generally, including chronic</p> | <p>1 inflammation, you would need more information</p> <p>2 in order to make the conclusion that that</p> <p>3 agent can in fact cause cancer, correct?</p> <p>4 MR. MEADOWS: Objection.</p> <p>5 THE WITNESS: You would look</p> <p>6 for more informative information,</p> <p>7 exactly, which is why, when I've</p> <p>8 talked about the individual</p> <p>9 constituents in the context of</p> <p>10 consistency on mechanism for cancer,</p> <p>11 I've pointed to documents where that</p> <p>12 information has been discussed.</p> <p>13 So like when I talk about</p> <p>14 asbestos or cobalt or I point to</p> <p>15 the -- for example, the IARC</p> <p>16 assessment where they go through</p> <p>17 that -- that discussion of the fact</p> <p>18 that there's not just data showing</p> <p>19 that a biologically plausible</p> <p>20 mechanism may be inflammation, but</p> <p>21 there's also data to show that that</p> <p>22 can lead to tumor development as well.</p> <p>23 QUESTIONS BY MS. BRANSCOME:</p> <p>24 Q. Okay. How does talc change the</p> <p>25 phenotype of the ovarian cell?</p> |

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| <p>1 A. So this is one of the details 2 we don't know, other than generally it's 3 changing the phenotype to go from a normal 4 cell to a tumor cell. That is being 5 observed. When you find the presence of the 6 tumor, that is what you're observing. 7 Q. Does pure talc with no other 8 constituent components, can it change the 9 phenotype of an ovarian cell? 10 MR. MEADOWS: Objection. 11 THE WITNESS: So that's a 12 difficult question to answer with 13 certainty because of the fact that I 14 don't believe that we have assurance 15 that any of the studies are done with 16 essentially pure talc. 17 However, in the studies that 18 claim to have been done with pure 19 talc -- for example, the NTP study 20 claims to have been done with pure 21 talc. So if that is pure talc, truly 22 is, then that study is an example of 23 evidence for the chronic inflammatory 24 process leading to preneoplastic 25 lesions that are setting down the road</p> | <p>1 in vitro or an animal experiment -- by which 2 you would expose either cells or animal to 3 talc with different constituent products to 4 identify or separate out the individual 5 effects of the components? Is that a study 6 that you could design as a toxicologist? 7 A. I think that would be difficult 8 to do, but I'm not saying impossible to do. 9 And here's the -- there are some very 10 specific considerations you'd have to put 11 into that design. 12 I would argue that some of that 13 is already available, where we have studies 14 that have looked at the dose-response effects 15 for toxicity with cobalt, with chromium, with 16 asbestos. 17 When you get to asbestos and 18 talc, it's more problematic because then the 19 question is what is -- what is it? What are 20 the specific characteristics in all the 21 different studies of exactly what the 22 asbestos was versus exactly what the talc 23 was. 24 But I think you could attempt 25 to do that, and then the question would be,</p> |
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| <p>1 mechanism towards cancer. 2 So there are data out there. 3 The problem you have, I believe, in 4 the literature is whether or not, 5 based on the discussion that is 6 becoming apparent now with sensitivity 7 and ability to take the natural 8 product and actually determine exactly 9 what's in it, that I don't think there 10 is the ability to assure that any -- 11 any of these studies with the samples 12 of talc they're using is absolutely, 13 100 percent, only platy talc. I think 14 there's -- there's some concern about 15 that. But certainly you will take -- 16 you have to take what is discussed 17 within the study as evidence from what 18 they're claiming. 19 So many of the studies say we 20 used asbestos-free talc or platy -- 21 pure platy talc and we got a toxic 22 response. 23 QUESTIONS BY MS. BRANSCOME: 24 Q. Would it be possible to design 25 an experiment -- and now I'm talking about an</p> | <p>1 being able to use that data not so much to -- 2 not so much to identify a dose response for a 3 certain insult, but to look at the fact -- 4 look at potency differences across the 5 compounds. And then there's the issue of 6 then looking at additivity when you know you 7 have a complex mixture. 8 So that could be done, but, 9 again, it would be difficult to do based on 10 what we know about talc, being able to really 11 know that -- you would have to really be very 12 careful that what it is that you're looking 13 at is -- is not containing any of those 14 things that we unfortunately know co-occur 15 with constituents within the natural product. 16 But no one has done those 17 studies. I point that out. I haven't seen 18 that study that you're asking for. I have 19 not seen somebody do that. 20 Q. And a study like that would be 21 relevant in evaluating the potency of the 22 individual constituents and what might 23 actually be the driving factor for phenotypic 24 change, correct? 25 A. Not necessarily. I would argue</p> |

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| <p>1 that we already have an answer to that by 2 looking at the data that's been collected on 3 the complex mixture itself. So the issue 4 would be why -- the question is what do you 5 gain by being able to say that we're only 6 pointing to this constituent or that 7 constituent. That isn't what is occurring. 8 What people are exposed to is 9 the complex mixture, not just each one of 10 those individual components. To me this is 11 not a case of asbestos-only exposure. This 12 is a case of exposure to consumer products 13 that are talc that may have within them at 14 any given time -- and data indicates that 15 there are substantial chance that asbestos 16 may be in -- is in certain of these products. 17 But my opinions are not 18 dependent on there being asbestos there at a 19 particular level or copper there -- or, I'm 20 sorry, cobalt there at a particular level 21 because my opinions are based on the 22 observations we have on the complex product 23 as it exists. 24 Q. And you recognize that 25 different types of talc and different talc</p> | <p>1 been linked to an inflammatory response. 2 Oxidative stress is often a triggering 3 mechanism. 4 Q. Does the body have protective 5 mechanisms that limit tissue damage from 6 oxidative stress? 7 A. Yes, which is why not everybody 8 that's exposed to any particular chemical is 9 going to get cancer. Some people will 10 respond better. Some cells will respond 11 better. Some individuals in a population at 12 one time in their life may respond better. 13 Q. You would agree that in vitro 14 studies do not account for the body's natural 15 defenses outside of what exists at the 16 cellular level, correct? 17 A. Depends on the in vitro study 18 that's being done and whether or not there is 19 components added. 20 So I've seen studies done where 21 they take cells and then add extra levels of 22 glutathione to try to protect the cells from 23 certain stressors that could lead to damage, 24 but I agree with you that an isolated cell on 25 its own is a different microenvironment than</p> |
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| <p>1 products have different constituent 2 components in different amounts, correct? 3 A. Some can. I agree with that. 4 That is true. 5 So if you're being broad, as in 6 pharmaceutical-grade versus industrial-grade 7 or chemical-grade, yeah, because they'll have 8 a purity level assigned. 9 But as far as what the -- what 10 the components are, it isn't always defined 11 even specifically within that. 12 Q. Okay. And does the presence of 13 oxidative stress in a tissue indicate that 14 cancer will develop in that tissue? 15 A. Will definitively develop? 16 Not -- I don't think you could say 17 definitively develop, but it's certainly in 18 the biologically plausible mechanism that's 19 been understood to lead to chronic 20 inflammation and also has been linked to 21 cancer. 22 So that's the issue of not 23 necessarily saying it has to be there, but it 24 certainly is something that is observed 25 routinely in cases where carcinogenesis has</p> | <p>1 an intact tissue, which is a different 2 environment than an intact animal, which is 3 even different than an intact human being. 4 Yes, they're all -- you look at those levels 5 of evidence or those types of evidence 6 differently, depending upon the end points 7 you're collecting. 8 Q. And so you would give lower 9 weight to an in vitro study as compared to an 10 in vivo study, for example? 11 A. Depends on the question you're 12 asking. I would give a lot of weight if the 13 question is what do I know -- if I want to 14 try to understand the biologically plausible 15 mechanism, some of those in vitro studies are 16 some of the most important, because it's the 17 only ones that allow us to answer a question. 18 If the question is higher level 19 about what is the evidence to show that 20 there's an increased risk overall for cancer 21 or a hazard for cancer, then certainly you 22 need to have more than an in vitro study. 23 So as -- so on -- if you want 24 to layer it up, obviously, if all you had was 25 in vitro data, you'd have much less</p> |

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| <p>1 confidence in the conclusions you can draw</p> <p>2 unless you had some in vivo data. In vivo</p> <p>3 data is going to allow you to interpret the</p> <p>4 in vitro data.</p> <p>5 So certainly there would be</p> <p>6 more weight given in that assessment to the</p> <p>7 fact that you had in vivo data.</p> <p>8 Q. And so when you made the</p> <p>9 statement that, for instance, you always give</p> <p>10 more weight to human data, is that true, or</p> <p>11 does that also depend?</p> <p>12 A. Well, it depends on whether you</p> <p>13 have human data. So if I have human data and</p> <p>14 I have a doubt, any doubts at all, about</p> <p>15 whether or not the exposure-response</p> <p>16 relationship would be affected by the way the</p> <p>17 animal studies are designed, then, yes, I</p> <p>18 would give more weight to the human studies.</p> <p>19 In a case, however, such as</p> <p>20 inhalation exposure assessments where</p> <p>21 there -- it's much better, actually, to do an</p> <p>22 animal study where we can do a dose response</p> <p>23 across different sizes of particles and</p> <p>24 actually observe lesions as they develop over</p> <p>25 time, which is why I love -- I love the NTP</p> | <p>1 weight, but it could if you only had one</p> <p>2 crappy human study, one really badly designed</p> <p>3 human study, and I had a GLP quality cancer</p> <p>4 bioassay then, absolutely. I mean, IARC does</p> <p>5 this. They look at that animal data and say,</p> <p>6 "This one tells us -- answers the questions</p> <p>7 we want to answer, and this very poorly</p> <p>8 designed case series isn't going to allow us</p> <p>9 to do that."</p> <p>10 So you could, but I would say</p> <p>11 it's more the other issue, that you look at</p> <p>12 animal and human more on an equal basis if</p> <p>13 the relevance and the extrapolation can be</p> <p>14 done reliably.</p> <p>15 And that's the question you</p> <p>16 have to ask, can I extrapolate from animals</p> <p>17 to humans in a reliable manner.</p> <p>18 Q. Okay. Would you agree that the</p> <p>19 response to cosmetic talc can vary depending</p> <p>20 on tissue type in the body?</p> <p>21 A. Yes, I would say that that is</p> <p>22 true, whether or not there's certain</p> <p>23 protective barriers in place, for example,</p> <p>24 yes.</p> <p>25 Q. And so in order to draw</p> |
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| <p>1 93 study of interim sacrifices, looking at</p> <p>2 that issue. That data is very reliable in</p> <p>3 order to understand the risk of lung damage</p> <p>4 as compared to a human study where we don't</p> <p>5 have those serial time points, doses that are</p> <p>6 defined tightly.</p> <p>7 So -- and the relevance between</p> <p>8 those kinds of initial lung injury in certain</p> <p>9 animals versus humans match fairly well.</p> <p>10 That's my problem, though, in</p> <p>11 the case with the perineal exposure. I'm</p> <p>12 saying to you, because of the route of</p> <p>13 contact -- we need to be able to get it there</p> <p>14 to the tissue -- the human data is extremely</p> <p>15 important.</p> <p>16 Q. So is it fair to say that in</p> <p>17 some circumstances animal data gets more</p> <p>18 weight than human data and in other</p> <p>19 circumstances human data gets more weight</p> <p>20 than animal data? It is circumstance</p> <p>21 dependent?</p> <p>22 A. I would put it a different way.</p> <p>23 I would say in some cases animal data is</p> <p>24 weighted in a similar manner to human data.</p> <p>25 I don't necessarily say it would get more</p> | <p>1 conclusions based on a study of one cell</p> <p>2 type's reaction to cosmetic talc to another,</p> <p>3 you would need to understand the differences</p> <p>4 in similarities between those two cell types,</p> <p>5 correct?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 THE WITNESS: It's a different</p> <p>8 question. So you were asking me</p> <p>9 about -- I didn't think you were just</p> <p>10 asking about cells. I thought you</p> <p>11 were asking me about like routes of</p> <p>12 exposure, dermal versus inhalation.</p> <p>13 Those things differ.</p> <p>14 Cell types may or may not.</p> <p>15 That may or may not be true. Because</p> <p>16 if two cells -- two different cell</p> <p>17 types in the body share similar</p> <p>18 characteristics as far as the -- for</p> <p>19 example, if they're both epithelial</p> <p>20 cells or mesothelial cells, those type</p> <p>21 of cells you would expect to respond</p> <p>22 the same way.</p> <p>23 But I would agree that, for</p> <p>24 example, a neuronal cell versus a GI</p> <p>25 cell versus a liver cell, there could</p> |

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| <p>1 be differences in how they would</p> <p>2 respond, yes, and so you would -- you</p> <p>3 would look at those things</p> <p>4 individually.</p> <p>5 QUESTIONS BY MS. BRANSCOME:</p> <p>6 Q. And so it's important to</p> <p>7 understand the differences and the</p> <p>8 similarities between the different cell types</p> <p>9 before drawing conclusions using studies from</p> <p>10 different cell types?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 MR. MEADOWS: Objection.</p> <p>13 THE WITNESS: I certainly think</p> <p>14 you should consider the cell types</p> <p>15 that are being used and whether or not</p> <p>16 those cell types are ones that are</p> <p>17 relevant to your risk assessment</p> <p>18 question you're asking, yes.</p> <p>19 QUESTIONS BY MS. BRANSCOME:</p> <p>20 Q. Okay. You would agree as a</p> <p>21 toxicologist, dose is an important part of a</p> <p>22 toxicological analysis of an agent, correct?</p> <p>23 A. If you're doing risk, yes. If</p> <p>24 you're only doing hazard, it may not be as</p> <p>25 important. It depends upon the question</p> | <p>1 Q. Okay. And in your -- in your</p> <p>2 report, as part of your risk assessment that</p> <p>3 you did in the MDL -- this is paragraph 12 on</p> <p>4 page 8.</p> <p>5 A. Yes, I'm there.</p> <p>6 Q. Okay. You state about</p> <p>7 two-thirds of the way down the paragraph that</p> <p>8 "weight of the evidence methods were critical</p> <p>9 to defining the literature that identified</p> <p>10 the hazards of talc exposure as well as</p> <p>11 defining the dose-response relationship</p> <p>12 between talc exposure and the risk of adverse</p> <p>13 health effects."</p> <p>14 Did I read that correctly?</p> <p>15 A. You did. That's correct.</p> <p>16 Q. All right. Is it your view</p> <p>17 that in the case you have reached an opinion</p> <p>18 that defines the dose-response relationship</p> <p>19 between talc exposure and the risk of ovarian</p> <p>20 cancer?</p> <p>21 A. It depends what you mean by</p> <p>22 define. I can tell you what I mean in this</p> <p>23 sentence, and maybe that would help you.</p> <p>24 Q. Dr. Plunkett, it is your</p> <p>25 report. And so I am asking you, using your</p> |
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| <p>1 you're asking about hazard.</p> <p>2 Do you want me to explain?</p> <p>3 Q. I do want you to explain the</p> <p>4 difference between a risk analysis and a</p> <p>5 hazard analysis.</p> <p>6 A. Okay. So in an initial hazard</p> <p>7 analysis, if the question is, is there a</p> <p>8 hazard associated with exposure, let's say,</p> <p>9 by inhalation, it may not matter whether it</p> <p>10 was a high dose or a low dose study. Both of</p> <p>11 those can identify hazard.</p> <p>12 Then you ask the question: Is</p> <p>13 there a dose-response relationship? That's</p> <p>14 the next step beyond hazard.</p> <p>15 So hazard is -- to me is</p> <p>16 identifying the end points that you're going</p> <p>17 to monitor for toxicity, sort of the target</p> <p>18 organs, those things, and so whether or not</p> <p>19 there's a dose-response study available, it</p> <p>20 wouldn't be as important.</p> <p>21 But certainly when you go to</p> <p>22 that next step to assess risk, you'd like to</p> <p>23 be able to see whether or not there is a</p> <p>24 dose-response relationship in the effect that</p> <p>25 you're assessing.</p> | <p>1 own definition of "define," have you rendered</p> <p>2 an opinion that defines the dose-response</p> <p>3 relationship between talc exposure and the</p> <p>4 risk of ovarian cancer?</p> <p>5 A. I have formed opinions about</p> <p>6 the dose-response relationship generally, but</p> <p>7 unfortunately -- I answered that question for</p> <p>8 you earlier when you asked me, I think, about</p> <p>9 is there -- I don't know if you used the word</p> <p>10 "threshold," but I did.</p> <p>11 So the available information</p> <p>12 doesn't allow us to identify an ultimate</p> <p>13 threshold, for example, in the case of women</p> <p>14 exposed to talc perineally and their -- and</p> <p>15 their development of ovarian cancer.</p> <p>16 Instead, in defining the dose</p> <p>17 response, what we can do with the data -- and</p> <p>18 that is what I attempted to do. This is</p> <p>19 where you look at defining the dose response</p> <p>20 in the animal studies, which we can look at,</p> <p>21 or defining dose response in cell studies,</p> <p>22 showing that as the dose increases, the</p> <p>23 hazard and the risk increase. So risk</p> <p>24 actually you quantify. There's a certain</p> <p>25 response at this dose and a different</p> |

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| <p>1 response at the next dose, or have we 2 plateaued, that the responses are the same as 3 dose increases. 4 So that, I did do that as part 5 of my assessment, trying to define the dose 6 as far as how that linked to the responses in 7 each of the studies I looked at. 8 Q. You would agree, though, that 9 some studies did not show a dose relationship 10 between talc and ovarian cancer or the 11 clinical signs that were indicative of the 12 potential for development into ovarian 13 cancer, correct? 14 MS. PARFITT: Objection. 15 THE WITNESS: If you're talking 16 about the human data; is that what 17 you're referring to? Or are you 18 talking about all -- any of the data? 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Any of the data. 21 A. So I would disagree on the 22 animal data. I think on the animal data they 23 often -- most of the animal studies I've 24 relied upon have looked at more than one dose 25 or at least looked a no exposure versus a</p> | <p>1 or -- that they may make a -- an 2 author may make a statement, but I'm 3 talking about looking -- this is 4 weight of the evidence. I'm looking 5 across. And I'm saying, across the 6 data, when I look at the human data 7 versus the animal data, for example, 8 versus in vitro studies, the in vitro 9 studies and the animal studies allow 10 you to look at dose response for talc 11 toxicity. 12 The -- even the animal studies 13 allow you to look at dose response for 14 development of precancerous lesions, 15 you're on the way to cancer, for 16 example, in the NTP studies. 17 And then in the human studies, 18 some of those studies are designed 19 such that the authors could draw 20 conclusions about dose response and 21 some are not. 22 Even in some of the studies 23 where they attempted to look at dose 24 response, some of the authors indicate 25 they don't see an effect. So that is</p> |
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| <p>1 dose, and most of them have looked at more 2 than one dose. 3 In the case of the human 4 studies, unfortunately, some of those studies 5 were not designed to be able to define dose. 6 In other words, the questions weren't asked, 7 for example, of the individuals even in the 8 prospective studies. Some of those 9 included -- did not include the information 10 collected on frequency and duration of use. 11 So if it's not collected, 12 obviously, I don't have it to look at. And 13 that's one of the limitations of human 14 epidemiological investigations, is that it 15 often is not designed appropriately to look 16 at dose response. 17 Q. Is it your opinion that there 18 are no studies looking at talc and the risk 19 of ovarian cancer in which the authors of the 20 study have concluded there was no clear 21 pattern of increased risk with dose? 22 MS. PARFITT: Objection. 23 THE WITNESS: No, that's not 24 what I've said. No. It's very 25 possible that an individual paper</p> | <p>1 true. And part of that may be driven 2 by the design of the study, the number 3 of individuals in the study, the way 4 that the questions were asked. 5 There's limitations on the way that 6 information is collected. 7 If you want to look at each 8 study, we can, but -- 9 QUESTIONS BY MS. BRANSCOME: 10 Q. So my question to you, whether 11 you agree or disagree with the author's 12 conclusion, is simply that if you look at the 13 overall animal and human studies that you 14 cite in your report or have considered on 15 your reliance list that look at a potential 16 dose-response relationship for talc toxicity, 17 do some of those studies conclude that there 18 is not a dose-response relationship? 19 MS. PARFITT: Objection. 20 THE WITNESS: I disagree for 21 talc toxicity, but I would say if 22 you're going to limit it to the issue 23 of the ovarian cancer response, I 24 would agree. I have seen that in some 25 of the studies.</p> |

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| <p>1 I think talc toxicity, I don't</p> <p>2 know if anybody has made the</p> <p>3 comment -- I would doubt it -- that</p> <p>4 there is no dose response for toxic</p> <p>5 effects of talc.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Okay. You discuss in your</p> <p>8 report -- wait a moment. It's in</p> <p>9 paragraph 58 on page 38. And I just want to</p> <p>10 make sure I understood what you were citing</p> <p>11 here.</p> <p>12 In paragraph 58 you state that</p> <p>13 "It is important to remember that</p> <p>14 administration of even a single dose of talc</p> <p>15 in animals has been shown to produce adverse</p> <p>16 effects locally at the site of the exposure."</p> <p>17 What are you referring to</p> <p>18 there?</p> <p>19 A. Acute doses. In other words,</p> <p>20 in studies that have described installation</p> <p>21 of a single dose of talc in some form into a</p> <p>22 tissue, that they are observing adverse</p> <p>23 responses.</p> <p>24 An example of that may be</p> <p>25 the -- I think it's Hamilton. Is that the</p> | <p>1 is that you give them less weight because you</p> <p>2 believe that the individuals who conducted</p> <p>3 the study had been paid by either a company</p> <p>4 or agencies that had some investment in the</p> <p>5 outcome of the study; is that correct?</p> <p>6 A. Is that my opinion?</p> <p>7 Q. Yes.</p> <p>8 A. For any particular study,</p> <p>9 you'll need to show me what you're pointing</p> <p>10 to. I do have opinions about some of the</p> <p>11 work by Drs. Huncharek and Muscat, yes. I</p> <p>12 think I address that specifically, and that</p> <p>13 has -- that's not so much to do with my</p> <p>14 weight of the evidence; that has more to do</p> <p>15 with transparency and what was being</p> <p>16 disseminated to the public and disseminated</p> <p>17 to the FDA as far as evaluations.</p> <p>18 That's a different issue than</p> <p>19 the weight of -- the weight of -- the weight</p> <p>20 of the evidence assessment for risk. I think</p> <p>21 those were separate.</p> <p>22 Q. So then I'll ask you that.</p> <p>23 In doing your weight of the</p> <p>24 evidence analysis for risk, have you</p> <p>25 discounted the weight that you've given to</p> |
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| <p>1 one where they stilled it into the ovaries</p> <p>2 with a single dose?</p> <p>3 Q. So these are large-dose</p> <p>4 exposures?</p> <p>5 A. Well, not all --</p> <p>6 Q. Or are they, I should say?</p> <p>7 A. I don't know that they all are,</p> <p>8 no. There are -- there are -- I don't think</p> <p>9 I have attempted to quantify large in this</p> <p>10 sentence.</p> <p>11 What I'm stating here is not an</p> <p>12 issue of large versus small. It's an issue</p> <p>13 of the fact that there are toxic effects with</p> <p>14 single exposures. And I'm just making the</p> <p>15 comment -- this has to do with hazard, right?</p> <p>16 It's the idea even a single dose -- or a</p> <p>17 single exposure you can get irritant,</p> <p>18 inflammatory reactions at the site of</p> <p>19 exposure. And that's all I'm trying to say.</p> <p>20 That's why I'm citing as reviewed by EPA. I</p> <p>21 believe EPA even makes a very similar</p> <p>22 statement.</p> <p>23 Q. Okay. Do you take into</p> <p>24 account -- there are some studies for</p> <p>25 which -- at least my reading of your report</p> | <p>1 any particular piece of scientific evidence</p> <p>2 based off of potential affiliations of the</p> <p>3 authors?</p> <p>4 A. I certainly did with the CIR</p> <p>5 review document. I've already told you that.</p> <p>6 And that's because I have evidence that shows</p> <p>7 it's not just an affiliation issue, but it's</p> <p>8 actually -- it's more -- it's more important</p> <p>9 than that.</p> <p>10 Q. Are there any other examples?</p> <p>11 A. I think that's the only one</p> <p>12 right now as I sit here that I can tell you</p> <p>13 that I had identified as carrying little</p> <p>14 weight because of an issue of either</p> <p>15 authorship or input in the way it was</p> <p>16 described.</p> <p>17 There are certainly studies</p> <p>18 within my weight of the evidence evaluation,</p> <p>19 some of which were performed by industry. I</p> <p>20 certainly look at that issue, but unless I</p> <p>21 have -- have a reason to believe that there's</p> <p>22 an inherent bias based on something I know,</p> <p>23 they go into the weight of the evidence</p> <p>24 without making a correction for that.</p> <p>25 In many cases that I work in</p> |

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|---|--|
| <p>1 litigation, I will find situations like the</p> <p>2 situation here with Huncharek and Muscat</p> <p>3 where I have, for example -- I think this</p> <p>4 came up in the Risperdal litigation for me.</p> <p>5 It's the idea that there was a series of</p> <p>6 papers put out by an individual investigator</p> <p>7 where documents that I could get access to</p> <p>8 show me that indeed their analysis was not</p> <p>9 done by them but it was ghostwritten by</p> <p>10 somebody else. So that gives me pause,</p> <p>11 although I would never have known that unless</p> <p>12 I had access to internal documents.</p> <p>13 So initial weight of the</p> <p>14 evidence I did not discount it, but then I</p> <p>15 went back and had to reevaluate the role</p> <p>16 those studies played in my overall</p> <p>17 assessment.</p> <p>18 Q. Do you take into account in any</p> <p>19 way in evaluating the weight of a study if it</p> <p>20 is conducted by someone who serves as an</p> <p>21 expert on behalf of the plaintiffs in the</p> <p>22 active litigation?</p> <p>23 A. It would be the same -- same</p> <p>24 issue. I certainly consider it as part of</p> <p>25 what I look at, but just like if they were an</p> | <p>1 tested, that he reports are Johnson's baby</p> <p>2 powder, did you also consider the work that</p> <p>3 was done by experts that have been retained</p> <p>4 on behalf of the defendants to characterize</p> <p>5 the components of Johnson's baby powder? Do</p> <p>6 you give them equal weight?</p> <p>7 A. So I haven't seen a variety of</p> <p>8 the documents that you're talking about,</p> <p>9 so -- because I have not worked in the</p> <p>10 litigation cases that have involved asbestos</p> <p>11 only. So -- which I think is where those</p> <p>12 documents are.</p> <p>13 In the litigation I -- in the</p> <p>14 litigation I worked in, I am aware of what</p> <p>15 other experts on both sides have said. I</p> <p>16 don't believe I've seen an analysis from a</p> <p>17 defense expert that is -- that is like</p> <p>18 Dr. Longo's, at least in the litigation I've</p> <p>19 worked in. Certainly I would consider that</p> <p>20 and look at that if it's available, and I</p> <p>21 would consider it.</p> <p>22 I would point out, Dr. Longo's</p> <p>23 analysis is not the piece of evidence that</p> <p>24 you start with, though. You start with what</p> <p>25 I discuss in the published literature first,</p> |
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| <p>1 expert for the defense versus an expert for</p> <p>2 the plaintiff, you judge that information</p> <p>3 based on what you know. And if I don't have</p> <p>4 information to discount it, I will not</p> <p>5 discount it.</p> <p>6 But absolutely, I understand.</p> <p>7 Just as people we all -- look at some of the</p> <p>8 things I've published where I have said my</p> <p>9 work was sponsored by the American Chemistry</p> <p>10 Council. You know, people -- that's why you</p> <p>11 disclose the conflicts. You put it there so</p> <p>12 people can weigh it if they want, but it</p> <p>13 doesn't mean you discount the work</p> <p>14 automatically.</p> <p>15 And so I think for any paper,</p> <p>16 plaintiff, defense, whoever it is that's</p> <p>17 writing it, you need to consider it based on</p> <p>18 the information you have. And if you believe</p> <p>19 that you have information to indicate that</p> <p>20 there's some issue with the reliability of</p> <p>21 the analysis, then absolutely you consider</p> <p>22 that.</p> <p>23 Q. So, for example, when you rely</p> <p>24 on Dr. Longo's characterization of the</p> <p>25 constituent components in samples that he has</p> | <p>1 because there are published documents out</p> <p>2 there in the literature that describe exactly</p> <p>3 what Dr. Longo is now describing.</p> <p>4 Q. What published documents are</p> <p>5 those?</p> <p>6 A. Those are Dr. Blount's reports</p> <p>7 in 1991, which is before the litigation came</p> <p>8 about, is my understanding.</p> <p>9 There's also -- there's five or</p> <p>10 six. I can tell you the paragraph.</p> <p>11 Q. For Johnson's baby powder, I</p> <p>12 would be interested in that, yes.</p> <p>13 A. So I -- I'll have to look and</p> <p>14 see if it's Johnson's baby powder only, but</p> <p>15 certainly there is other evidence on the</p> <p>16 issue of asbestos contamination and</p> <p>17 specifically in talc.</p> <p>18 So I -- you want me to find the</p> <p>19 paragraph for you?</p> <p>20 Q. Please. If you think there is</p> <p>21 published literature documenting asbestos in</p> <p>22 Johnson's baby powder, I would like to see</p> <p>23 that.</p> <p>24 A. So this is my paragraph 32.</p> <p>25 And I'd have to pull each of these articles</p> |

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| <p>1 out because I don't recall what each of them</p> <p>2 says. But I'm pointing to Paoletti, Blount,</p> <p>3 Mattenklott, Moon, Gordon, Anderson, Rohl,</p> <p>4 Pooley and Rowlands, Blejer and Arlon,</p> <p>5 Cralley, Millman.</p> <p>6 And then I cite -- and then of</p> <p>7 course the next piece of evidence is there</p> <p>8 are actually documents from J&J and Imerys</p> <p>9 that show detection of asbestos or</p> <p>10 asbestos-like minerals in talc.</p> <p>11 Q. As you sit here today, can you</p> <p>12 identify which of these published articles</p> <p>13 that you list in paragraph 32 relate to</p> <p>14 Johnson's baby powder?</p> <p>15 A. I would have to pull them to</p> <p>16 answer that.</p> <p>17 Q. Okay.</p> <p>18 A. As I sit here, I'd have to pull</p> <p>19 them. But I would refer you -- I know at</p> <p>20 least some of them do based on the statement</p> <p>21 I've made, but...</p> <p>22 Q. So you did not make an attempt</p> <p>23 in this paper to identify which products were</p> <p>24 being analyzed in these specific articles.</p> <p>25 It's not indicated on the face of this</p> | <p>1 look.</p> <p>2 Q. Have you reviewed Dr. Blount's</p> <p>3 deposition?</p> <p>4 A. I have reviewed a -- something</p> <p>5 by Dr. Blount. Whether it was trial</p> <p>6 testimony or deposition, I have seen</p> <p>7 something, yes, that she has said regarding</p> <p>8 this issue.</p> <p>9 Q. To the extent that there is</p> <p>10 confusion about whether or not a sample</p> <p>11 tested by Dr. Blount is in fact Johnson's</p> <p>12 baby powder, would you reduce the weight that</p> <p>13 you give that particular piece of evidence in</p> <p>14 evaluating whether asbestos has been present</p> <p>15 in Johnson's baby powder?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: I don't know</p> <p>19 reduce the weight because -- because</p> <p>20 there's -- there are plenty of</p> <p>21 documents here that talk about that.</p> <p>22 I would consider it --</p> <p>23 certainly it would -- it's not so much</p> <p>24 weight. It's a different bin. We'll</p> <p>25 call it a bin, a different bin of</p> |
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| <p>1 paragraph, correct?</p> <p>2 A. I don't tell you on the face,</p> <p>3 but you if read the sentence I said, "When</p> <p>4 commercially available, talcum powder</p> <p>5 products were analyzed, including powders</p> <p>6 sold by Johnson & Johnson. The data has</p> <p>7 shown that the powders contained varied</p> <p>8 levels" -- and I'm saying "fibers," so it's</p> <p>9 just asbestos -- "including fibers that</p> <p>10 stated to be asbestos."</p> <p>11 So to tell you which of those,</p> <p>12 I'd have to pull them. And I apologize, I</p> <p>13 didn't bring them all with me.</p> <p>14 Q. Have you been provided --</p> <p>15 you're aware that Dr. Blount's paper does not</p> <p>16 identify Johnson's baby powder in the face of</p> <p>17 the article, correct?</p> <p>18 A. I believe that's true. You'd</p> <p>19 have to go to her deposition, I believe,</p> <p>20 where she's given -- where she discusses what</p> <p>21 the source of that was, and maybe even a --</p> <p>22 there may even be a separate document,</p> <p>23 actually, not a deposition, that was -- that</p> <p>24 was in the files of Johnson & Johnson that</p> <p>25 goes along with that, but I'd have to go</p> | <p>1 information. There's information on</p> <p>2 talc powders generally, and then</p> <p>3 there's some information that's</p> <p>4 specific to certain body powders.</p> <p>5 So certainly -- would I pay</p> <p>6 attention if they identified it? Yes.</p> <p>7 But in the statement I'm making</p> <p>8 here, I'm not claiming that every one</p> <p>9 of these is relating to just the</p> <p>10 powder sold by Johnson & Johnson.</p> <p>11 This is across the available</p> <p>12 information that's public and then</p> <p>13 also the information that's available</p> <p>14 in the files of Johnson & Johnson.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. What is your definition of</p> <p>17 asbestos?</p> <p>18 A. My definition of asbestos is</p> <p>19 exactly what the different documents describe</p> <p>20 it typically. It's a fibrous mineral,</p> <p>21 typically. It occurs in a variety of</p> <p>22 different forms. Most of the times they'll</p> <p>23 say "asbestos." Sometimes they'll say</p> <p>24 "chrysotile." Sometimes they'll say</p> <p>25 "tremolite." Sometimes they'll say</p> |

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| <p>1 "anthophyllite." Those are the three most 2 common ones I see. But those are all mineral 3 forms of asbestos. 4 So just like IARC puts those 5 all within one bin, I'm putting those all in 6 one bin because they have a similar toxicity 7 profile. 8 Q. Is it your view that each of 9 the different types of asbestos has the same 10 toxicity profile? 11 A. They all have the same ability 12 to cause cancer, but they have different 13 potencies. So they do have -- there will be 14 some differences in the dose response and the 15 potency of them, but certainly they've all 16 been linked as being carcinogens by IARC. 17 And I would agree, when you 18 look at their data, there is data and 19 evidence to indicate that. 20 Q. Which type of asbestos is the 21 most potent? 22 A. For which end point? For lung 23 cancer? I believe chrysotile is. For other 24 end points, I'd have to go look. I mean, 25 chrysotile is the sharp -- is the sharp --</p> | <p>1 A. Has to do with the fact that we 2 have a complex mixture that has multiple 3 carcinogenic substances. 4 And asbestos is important from 5 the aspect of the way that it has been 6 assessed even by regulatory bodies, the idea 7 that even very low levels of fibers pose a 8 cancer hazard and a cancer risk in 9 individuals have been shown to be 10 carcinogenic. 11 So that's what I'm saying about 12 potency of asbestos is different than potency 13 of some other carcinogens that you might look 14 at. But the importance of it is it's a 15 complex mixture, talc, body powders, a 16 complex mixture that includes constituents 17 that are known human carcinogens as well as 18 some that are -- been ranked other ways by 19 regulatory bodies. 20 Q. If Johnson's talcum powder 21 products do not contain asbestos, does that 22 change your opinion with respect to the risk 23 they pose with respect to ovarian cancer? 24 A. No, and I think that was very 25 clear if you looked at my first report. So</p> |
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| <p>1 the sharded-type structure. 2 But there's data on fibrous -- 3 the fiber -- the fibrous forms of asbestos 4 rather than the -- or the amphibole forms of 5 asbestos as opposed to chrysotile, which is 6 the serpentine form. 7 Q. Do you consider yourself an 8 expert in asbestos? 9 A. Not in -- 10 MS. PARFITT: Objection. 11 THE WITNESS: Not the geology 12 of asbestos, no. 13 I have expertise in toxicology 14 as it relates to interpretation of the 15 data related to asbestos. I have 16 never give -- given testimony in a 17 case on asbestos, but it's something 18 I've studied in the past in my work as 19 a toxicologist, not as a testifying 20 expert. 21 QUESTIONS BY MS. BRANSCOME: 22 Q. What role does your analysis of 23 the possibility that there may be asbestos in 24 Johnson's talcum powder products play in your 25 risk assessment in the MDL?</p> | <p>1 even -- there's -- I don't think in any of my 2 reports I've opined that without looking at 3 the complex mixture that we wouldn't be here. 4 In other words, I have not 5 opined that if it doesn't have -- if it 6 doesn't have asbestos, it's not a risk. I 7 have not opined that, and I don't believe 8 that, because I think there is independent 9 risk for the fact that we have a complex 10 mixture of talc that has been tested and 11 shown to be carcinogenic. 12 It's my opinion, I told you -- 13 maybe it wasn't you. I may have told this 14 yesterday, I'm sorry, to Mr. Smith that I 15 believe that there is evidence to show that 16 there is a significant exposure to asbestos 17 based on the data that's been collected. 18 But certainly, you know, in 19 some -- the data has shown that in the assays 20 that have been done or the analyses that have 21 been done that you can't say that talc is 22 asbestos-free. 23 Q. Well, so -- 24 A. So -- 25 Q. -- the question I have</p> |

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| <p>1 specifically relates to ovarian cancer. 2 Is it your view that through an 3 exposure route that is relevant for ovarian 4 cancer, that the use of Johnson's talcum 5 products involve a substantial exposure to 6 asbestos? 7 A. I believe based on the use of 8 the products that -- where the data has been 9 collected that there would be a substantial 10 exposure to asbestos, regardless of how 11 you're exposed, perineal -- perineally or by 12 inhalation. 13 Q. What is your basis for reaching 14 that conclusion? 15 A. It's looking at the number of 16 fibers that have been detected in the 17 products, in looking at the -- the widespread 18 nature of the presence of asbestos fiber -- 19 asbestos in the talcum powder products and 20 the fact that even though it's at a very low 21 level by their -- their level of detection, 22 again, can't be said to be asbestos-free. 23 So regardless of whether it's 24 talc that's being applied perineally or a 25 talc that you're inhaling while you're</p> | <p>1 asbestos above background through the 2 perineal use of Johnson's talcum powder 3 products? 4 MR. MEADOWS: Objection. 5 MS. PARFITT: Objection. 6 THE WITNESS: I don't think 7 that's the opinion I have formed to 8 date, but certainly the opinion I have 9 formed is that the data I have seen 10 indicates that you can't separate out 11 talc without asbestos versus talc with 12 asbestos in the information that's 13 been collected. Because there's -- 14 all -- the information that's been 15 collected has shown there's no 16 evidence that asbestos-free talc is 17 available. 18 If by asking that question 19 you're trying to say that it's the 20 asbestos alone that's causing the 21 cancer, that is not my opinion. So 22 that is when the dose issue would 23 become very important for asbestos. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. Okay.</p> |
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| <p>1 applying it perineally, the fibers are still 2 going to be present within that talc. 3 Q. Have you or anyone done an 4 analysis of the dose of asbestos to which 5 someone might be exposed perineally? 6 A. I haven't done a specific 7 calculation, no. 8 Q. Has anyone done that 9 calculation? 10 MS. PARFITT: Objection. Form. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. That you have seen? 13 MS. PARFITT: Objection. 14 THE WITNESS: I'm trying to 15 remember whether I saw that done in 16 any of the documents related to 17 Dr. Longo. 18 I don't know. I'd have to go 19 look. 20 QUESTIONS BY MS. BRANSCOME: 21 Q. Okay. So as you sit here 22 today, can you give an opinion to a 23 scientific degree of certainty, reasonable 24 degree of scientific certainty, that an 25 individual would be exposed to a dose of</p> | <p>1 A. So that's -- so that's a 2 different question I have not answered. 3 Q. And in reaching your opinion 4 that there is no evidence that asbestos-free 5 talc exists, you have not been provided with 6 the reports by the defense experts, including 7 Dr. Matthew Sanchez, analyzing Johnson's 8 talcum powder products for the presence or 9 absence of asbestos, correct? 10 MS. PARFITT: Objection. Form. 11 I think you're aware that the 12 MDL expert reports have not yet been 13 provided to us. 14 MS. BRANSCOME: Yeah. 15 MS. PARFITT: I'm just making a 16 point. 17 THE WITNESS: I have not seen a 18 report by Dr. Sanchez. I assume I 19 will, because typically after -- later 20 in the litigation, once all experts 21 have been deposed or revealed, I'm 22 usually given defense expert reports 23 and their deposition testimony. So I 24 expect to see that; I just haven't 25 seen it yet.</p> |

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| <p>1 QUESTIONS BY MS. BRANSCOME:</p> <p>2 Q. And you haven't seen it in any</p> <p>3 of the cases in which you've rendered an</p> <p>4 opinion, correct, not just the MDL?</p> <p>5 A. Well, none of the cases that I</p> <p>6 have worked in have involved the issue of</p> <p>7 looking for asbestos exposure.</p> <p>8 The cases I have worked on have</p> <p>9 been talking about talc exposure that may</p> <p>10 include asbestos as a constituent, but it</p> <p>11 wasn't focused on asbestos exposure.</p> <p>12 So, no, none of the cases I</p> <p>13 worked on have provided testimony in that</p> <p>14 area.</p> <p>15 You understand what I'm saying?</p> <p>16 Q. Let me just make it clear. You</p> <p>17 have not, in any of the cases in which you</p> <p>18 have offered opinions with respect to the</p> <p>19 contents of talc, been provided with an</p> <p>20 expert report or testimony by Dr. Sanchez</p> <p>21 about what he did or did not find in</p> <p>22 Johnson's talcum powder products with respect</p> <p>23 to asbestos?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: So I can't tell</p> | <p>1 application for any of the heavy metals. So</p> <p>2 the three that I've mentioned, no, I have not</p> <p>3 done that calculation.</p> <p>4 Q. You would agree, based on your</p> <p>5 training and experience as a toxicologist,</p> <p>6 that in order for an agent -- and we can talk</p> <p>7 specifically about a metal -- to present a</p> <p>8 risk of cancer it needs to be bioaccessible,</p> <p>9 correct?</p> <p>10 A. If by bioaccessible you are not</p> <p>11 limiting that definition to solubilized into</p> <p>12 the blood and carried systematically, yes, I</p> <p>13 would agree with that. Bioaccessible meaning</p> <p>14 it has to be in a form that can somehow</p> <p>15 interact with the tissue, yes, I agree with</p> <p>16 that. But it could be as simple as tissue</p> <p>17 contact versus needing to be solubilized.</p> <p>18 Q. Okay. Is silica bioaccessible?</p> <p>19 A. It depends on the form of the</p> <p>20 silica. So silica particles can be</p> <p>21 bioaccessible if inhaled and found on the</p> <p>22 surface of the lung. That can cause injury</p> <p>23 at the site of the lung. So that's an</p> <p>24 accessibility to that particular tissue that</p> <p>25 it contacts.</p> |
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| <p>1 you that I have not. I don't recall</p> <p>2 it. That's all I can say. I don't</p> <p>3 recall that name.</p> <p>4 QUESTIONS BY MS. BRANSCOME:</p> <p>5 Q. It's certainly not something</p> <p>6 you discuss in your report, correct?</p> <p>7 A. No, I do not. And I don't know</p> <p>8 that it's in my reliance materials. That's</p> <p>9 why I'd ask you to look there, because if</p> <p>10 it's in my reliance materials, then I've seen</p> <p>11 it.</p> <p>12 Q. Okay.</p> <p>13 A. And I mean big reliance</p> <p>14 material list, not my reference list.</p> <p>15 Q. All right. With respect to the</p> <p>16 other potential constituents of talc, have</p> <p>17 you done any analysis to provide an answer as</p> <p>18 to how much -- what dose of chromium, for</p> <p>19 example, an individual might be exposed to</p> <p>20 through the perineal use of Johnson's talcum</p> <p>21 powder products over a lifetime?</p> <p>22 A. No, and I have -- well, I know</p> <p>23 it's a separate deposition. We discussed</p> <p>24 this yesterday. No, I have not done a -- a</p> <p>25 calculation of a potential dose with perineal</p> | <p>1 Q. We talked earlier -- it's</p> <p>2 somewhat related to bioaccessibility, but we</p> <p>3 talked about the way in which different</p> <p>4 particles might move specifically through the</p> <p>5 genital tract in women.</p> <p>6 Do you recall that?</p> <p>7 A. Yes. A general discussion.</p> <p>8 Q. Yes.</p> <p>9 And when you testified that</p> <p>10 starch and talc might not move at the same</p> <p>11 rate, do you have an opinion as to which</p> <p>12 might move more quickly through the tract?</p> <p>13 A. I haven't formed that opinion,</p> <p>14 no.</p> <p>15 Q. Okay. And do both talc and</p> <p>16 starch particles remain in the body for the</p> <p>17 same length of time?</p> <p>18 A. I haven't done an analysis to</p> <p>19 see if the data tells us what the -- what the</p> <p>20 differences might be. I would expect there</p> <p>21 to be differences, which is what I told you</p> <p>22 earlier, because I would expect the starch to</p> <p>23 be able to be solubilized, where I would not</p> <p>24 necessarily expect the talc to act in that</p> <p>25 same manner.</p> |

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| <p>1 Q. Is cornstarch capable of 2 causing an inflammatory process? 3 A. It can. It is -- but it is -- 4 it's a different level of risk for 5 inflammatory responses than is talc, just by 6 its chemical nature. 7 Q. Have you done an analysis in 8 your report that examines the differences 9 between the inflammatory response that can be 10 triggered by talc as opposed to cornstarch? 11 A. I haven't analyzed inflammatory 12 response. Instead, what I've done is done a 13 comparison of what the toxicity -- the 14 differences in the toxicity potential have 15 been described in medical literature, and I 16 cite -- I have a paragraph where I cite to 17 some sources that talk about the differences 18 in the toxicity potential or biocompatibility 19 of starch versus talc. 20 Q. Now, I had a question about 21 your supplemental report that was marked as 22 Exhibit 3 to the deposition. 23 At paragraph 67... 24 A. Okay. 25 Q. You identify here six heavy</p> | <p>1 only three heavy metals: chromium, cobalt 2 and nickel. 3 Do you see that? 4 A. Yes. 5 Q. Why did you remove three of the 6 heavy metals? 7 A. It's not so much removing. 8 Those three heavy metals that I focused on in 9 my MDL report are ones that have been talked 10 about with a similar mechanism of action as 11 far as irritation and biologic -- biologic 12 plausibility mechanism being irritation and 13 inflammation. 14 So that's why I focus on those 15 three, which may not -- which is not 16 necessarily the case for some of the others, 17 even though they're also -- have a 18 carcinogenic hazard, pose a risk. 19 Q. So in your -- as part of your 20 risk assessment that you performed in the 21 MDL, are you offering the opinion that to the 22 extent they exist in any of the Johnson 23 talcum powder products, that arsenic, lead -- 24 A. Cadmium. 25 Q. -- and cadmium play any role in</p> |
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| <p>1 metals - arsenic, chromium, lead, cobalt, 2 cadmium and nickel - that in your 3 supplemental report dated August 29, 2018, 4 you say have been reported across lots of 5 talc powders. 6 Do you see that? 7 A. Are you in -- now you're in my 8 MDL report or here? 9 Q. No. 10 A. Oh, so where are you? I'm 11 sorry. 12 Q. Same report. It's the sentence 13 that begins at the bottom of page 6. 14 A. Okay. Hold on. 15 About that they have varied at 16 the levels -- 17 Q. Yes. So you identify six 18 different types of heavy metals. 19 Do you see that there? 20 A. Yes, I do. 21 Q. Okay. And the question I had 22 for you was that in your report in the MDL, 23 if you look at paragraph 36 -- 24 A. Yes. 25 Q. -- you identify -- you identify</p> | <p>1 the risk of developing ovarian cancer? 2 A. That is not an opinion that I 3 would be offering in the MDL. 4 Q. Okay. Now, you talk about 5 these heavy metals having been classified by 6 different agencies as either known probable 7 or possible human carcinogens, correct? 8 A. You're in my MDL report again? 9 Q. Oh, yes. 10 A. Okay. I'm sorry. Okay. Let 11 me get there. 12 Yeah, I do have that 13 discussion. I'm just trying to find it. 14 Q. Sure. 15 A. Okay. Yes, I'm there. 16 Q. Is it your view, based on your 17 expertise, that because a compound can cause 18 one type of cancer, it can cause all types of 19 cancer? 20 A. No, not necessarily. It 21 depends on the -- well, it depends on a 22 couple of things. It depends on what's been 23 studied. Have all types of cancer even been 24 studied. And then it also -- it also depends 25 upon, I believe, the route of exposure as</p> |

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| <p>1 well. So can it get to where it could cause 2 that, could it distribute there. And then in 3 addition to that, what data has been 4 collected. Is there enough data, for 5 example, to show that there's extrapolation 6 from animals to humans in the types of tumors 7 or is it -- or if we have good human data, 8 then we would focus on the types of cancers 9 that you're seeing in humans, for example. 10 Q. Okay. But you recognize even 11 where there is complete data some compounds 12 can cause one type of cancer and they are 13 incapable of causing another type, correct? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: I don't know 16 about incapable, but I would agree 17 that you certainly would see -- you 18 could potentially see different 19 observations. 20 If you're talking about animals 21 versus humans, or are you talking 22 about -- 23 QUESTIONS BY MS. BRANSCOME: 24 Q. If humans. 25 A. Based on what you had seen in</p> | <p>1 you can extrapolate with scientific basis 2 from one type of cancer cause to ovarian 3 cancer with respect to the heavy metals 4 specifically? 5 A. Well, I haven't attempted to 6 that, because I haven't attempted to define a 7 independent risk for each of those metals 8 individually. 9 The issue -- the issue I have 10 with those metals is -- there's a paragraph 11 here where I talk about pathogenesis of 12 carcinogenesis, where I talk about different 13 stages of cancer development and the fact 14 that inflammatory responses may be operating 15 at all those different stages. 16 So the issue is you have 17 potential -- you have compounds that are 18 known to produce cancer or have been shown to 19 have a potential risk of cancer. They share 20 a similar mechanism to talc, so as a result 21 of that, they factor into your risk 22 assessment as far as there being an exposure 23 to a mixture. 24 But on the issue of ovarian 25 cancer, I'm looking at the data that's been</p> |
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| <p>1 the animals; is that what you're asking me? 2 Q. Yes. 3 A. Yes. So, yes, there is not 4 always a one-to-one concordance. So that's 5 why -- that's why I made the comment that 6 it's important to have some human data or 7 experience, so that you can put in context 8 the data you collected in animals. 9 I would say to you there are 10 certain kinds of tumors in animals, for 11 example, that are shown to be not relevant at 12 all to human risk assessment. Like four 13 stomach tumors in rats is an example. I've 14 dealt with that one a lot. 15 Q. What types of cancer -- type or 16 types of cancer are the basis for the 17 classification of chromium as a known human 18 carcinogen by IARC? 19 A. So I have to pull it out, but I 20 believe that there may be some GI cancers and 21 maybe some skin cancers, but I'm not sure. 22 I've got it pull it out. It's been a while 23 since I've looked at it. 24 Q. Okay. Have you done an 25 analysis to evaluate whether or not the types</p> | <p>1 collected on talc itself, which would be talc 2 with the constituents that could include the 3 metals. But certainly I'm not saying that it 4 is -- without the presence of one or the 5 other of these there would be no risk of 6 ovarian cancer. I'm not saying that either. 7 Q. So my question is, though, can 8 you point me either to scientific literature 9 directly documenting that these heavy metals 10 can cause ovarian cancer or to scientific 11 literature that enables you to extrapolate 12 from the types of cancer that they are known 13 or believed to cause to ovarian cancer? 14 A. So I -- on the issue of can I 15 point you to the data on ovarian cancer, I'd 16 have to go back. I can't answer that without 17 looking at the assessments. 18 But on the other -- second 19 question you asked me, that's the question I 20 was just trying to answer before. It's the 21 idea that regardless of where the cancer is 22 developing, the fact that these compounds 23 have the ability to stimulate similar toxic 24 responses in tissues could lead to a -- 25 setting up a situation where the -- where the</p> |

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| <p>1 tissue is primed for cancer development.</p> <p>2 Q. And do you have --</p> <p>3 A. And so that --</p> <p>4 Q. Sorry.</p> <p>5 A. And that has to do with the</p> <p>6 basic science of carcinogenesis when you look</p> <p>7 at underlying mechanisms, especially with</p> <p>8 tissue contact, direct tissue contact, with</p> <p>9 irritants or inflammatory processes.</p> <p>10 But I would -- I am not -- I</p> <p>11 have not formed the opinion, again, that with</p> <p>12 or without either one of these that I would</p> <p>13 expect ovarian cancer to be the target. I'm</p> <p>14 saying that ovarian cancer risk is increased</p> <p>15 based on exposure to talc, which includes a</p> <p>16 variety of constituents.</p> <p>17 Q. Okay. And do you cite anywhere</p> <p>18 in your report to studies documenting -- I</p> <p>19 know you said you'd need to go look at them,</p> <p>20 but I'm asking if it's in your report</p> <p>21 anywhere a discussion of any studies showing</p> <p>22 that the particular heavy metals that you</p> <p>23 cite as potential constituents of Johnson &</p> <p>24 Johnson's products have been demonstrated to</p> <p>25 increase a risk for ovarian cancer on their</p> | <p>1 So, again, that's what I'm</p> <p>2 pointing to and why I have cited the data.</p> <p>3 Q. Now, you talked about -- when</p> <p>4 we were discussing mechanism, you said that</p> <p>5 inflammation alone is not necessarily</p> <p>6 sufficient to cause cancer, correct?</p> <p>7 A. Yes, I did.</p> <p>8 Q. All right. Do you have</p> <p>9 scientific studies that show that any of the</p> <p>10 heavy metals or the fragrance constituents</p> <p>11 that you identify as potential carcinogens</p> <p>12 create -- generate phenotypic changes like</p> <p>13 you discussed were next for the formation of</p> <p>14 cancer?</p> <p>15 A. I believe that data is</p> <p>16 available on nickel. I need to go back and</p> <p>17 look at chromium and cobalt, but I do believe</p> <p>18 with nickel you'll find similar data on</p> <p>19 tissue irritation and inflammatory processes.</p> <p>20 Nickel is also a sensitizer, so</p> <p>21 it has interaction with the immune system, so</p> <p>22 I do believe that for nickel you can find</p> <p>23 some of that data.</p> <p>24 Q. Okay. But as you sit here</p> <p>25 today, can you point me into any of that</p> |
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| <p>1 own?</p> <p>2 A. So, no, I haven't addressed</p> <p>3 that in my report. And again, I think that's</p> <p>4 inconsistent with the way I'm using these</p> <p>5 data. But that's fine. I mean, no, I</p> <p>6 haven't done a specific assessment of ovarian</p> <p>7 cancer risk with each of those metals</p> <p>8 individually.</p> <p>9 Q. I would ask the same questions</p> <p>10 for the different fragrance constituents that</p> <p>11 you allege in your report are potential</p> <p>12 carcinogens.</p> <p>13 Have you done any analysis, and</p> <p>14 can you point me to any scientific studies</p> <p>15 that establish that those particular</p> <p>16 compounds are capable of causing ovarian</p> <p>17 cancer?</p> <p>18 A. No, I haven't done that</p> <p>19 analysis, but, again, general principles of</p> <p>20 toxicology and cancer risk assessment, when</p> <p>21 you look at the presence of multiple --</p> <p>22 excuse me, multiple carcinogens with similar</p> <p>23 mechanisms of action, you would assume in</p> <p>24 your risk assessment that those risks could</p> <p>25 be additive.</p> | <p>1 that's discussed in your report?</p> <p>2 A. No specific discussion other</p> <p>3 than, again, all -- the IARC -- I'm citing to</p> <p>4 the IARC assessments, and the IARC</p> <p>5 assessments for each of those discuss</p> <p>6 carcinogenesis and a biologically plausible</p> <p>7 mechanism being linked to the ability of</p> <p>8 these compounds to induce oxidative stress</p> <p>9 and/or inflammatory processes.</p> <p>10 Q. Okay. In your opinion, you</p> <p>11 talk about the mixture of constituents that</p> <p>12 are involved in talc.</p> <p>13 Have you done any analysis to</p> <p>14 look at how the different constituents</p> <p>15 interact with each other?</p> <p>16 A. Well, yes, that's my issue at</p> <p>17 looking at underlying mechanism.</p> <p>18 But are you asking me -- I</p> <p>19 certainly don't have a -- the only studies</p> <p>20 that I have to rely upon on the interaction</p> <p>21 of the mixture is the actual studies on the</p> <p>22 powders themselves, where we know that the</p> <p>23 powders contain constituents other than just</p> <p>24 platy talc.</p> <p>25 Q. Okay. And do the constituents</p> |

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| <p>1 need to have the same underlying potential</p> <p>2 carcinogenic mechanism for them to have an</p> <p>3 additive effect?</p> <p>4 A. By general principles of</p> <p>5 toxicology, yes, you look at mode -- mode of</p> <p>6 action or mechanism of action before you</p> <p>7 apply that additivity principle to the cancer</p> <p>8 risk assessment.</p> <p>9 Q. And so as you sit here, you</p> <p>10 believe there have been scientific</p> <p>11 documentation that nickel might operate</p> <p>12 through the same biological mechanism as you</p> <p>13 purport talc to operate, but you're not sure</p> <p>14 about the other heavy metals or the fragrance</p> <p>15 constituents; is that correct?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 THE WITNESS: For the fragrance</p> <p>18 constituents, I'd definitely have to</p> <p>19 pull because I haven't looked at that</p> <p>20 individual assessment in a while.</p> <p>21 For these three, what I do know</p> <p>22 is that they do share the ability to</p> <p>23 at least induce oxidative stress.</p> <p>24 What I can't recall for</p> <p>25 chromium and for cobalt is whether</p> | <p>1 So those two -- we'd have human data</p> <p>2 to show that.</p> <p>3 But on the issue of cobalt, it</p> <p>4 may only be -- I need to go back and</p> <p>5 look, but it may indeed just be animal</p> <p>6 data.</p> <p>7 QUESTIONS BY MS. BRANSCOME:</p> <p>8 Q. And so your basis for that</p> <p>9 would be the IARC classification?</p> <p>10 Is that where I would go to</p> <p>11 look if I wanted to look at it after this</p> <p>12 deposition?</p> <p>13 A. I'd go to the IARC reviews.</p> <p>14 I'd go to those three which I believe I have</p> <p>15 cited down here for you and given you where</p> <p>16 to go to find them.</p> <p>17 Q. Okay. You discuss in your</p> <p>18 report -- and if you'd like to reference it,</p> <p>19 it's paragraph 69 on page 47 -- the concept</p> <p>20 of genotoxic and nongenotoxic carcinogens.</p> <p>21 Do you recall that?</p> <p>22 A. Yes.</p> <p>23 Q. And as you sit here today, is</p> <p>24 it your opinion that talc is more likely a</p> <p>25 nongenotoxic carcinogen?</p> |
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| <p>1 they're taking it the next step from</p> <p>2 oxidative stress to inflammatory</p> <p>3 process. I believe that they do, but</p> <p>4 I'd have to check, whereas I know</p> <p>5 nickel has been shown to lead to an</p> <p>6 inflammatory process after oxidative</p> <p>7 stress has been induced.</p> <p>8 QUESTIONS BY MS. BRANSCOME:</p> <p>9 Q. And you would agree, even more</p> <p>10 than requiring an inflammatory process, you</p> <p>11 would actually have to see that these</p> <p>12 compounds can generate phenotypic changes,</p> <p>13 correct?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: Well, we know</p> <p>16 they do because they've been shown to</p> <p>17 be carcinogenic. If you've been shown</p> <p>18 to be carcinogenic, you've done a</p> <p>19 phenotypic change in the cell from a</p> <p>20 normal cell to a cancer cell.</p> <p>21 So we know they have the</p> <p>22 capability to induce tumors, or</p> <p>23 cancer, all three of those, at least</p> <p>24 in animals if not in humans as well,</p> <p>25 because two of them are known human.</p> | <p>1 A. As the direct insult, yes. And</p> <p>2 I would like to -- I would like to point out</p> <p>3 that in the literature -- the reason I have</p> <p>4 this paragraph here is because in the</p> <p>5 literature in the past, in the area of</p> <p>6 chemicals, it's been -- toxicologists have</p> <p>7 attempted to put two bins, direct genotoxic</p> <p>8 insult versus nondirect genotoxic. It</p> <p>9 doesn't mean you can't get a genotoxic event</p> <p>10 after the initiation.</p> <p>11 So I want to make sure you</p> <p>12 understand that. I'm not saying that there</p> <p>13 is no possibility of this chemical in its --</p> <p>14 in its process of inducing cancer leading to</p> <p>15 indirect genotoxicity, but I'm talking about</p> <p>16 the direct mechanism at the site of the cell.</p> <p>17 So talc, for example, has been</p> <p>18 shown to not be genotoxic in cells. And so</p> <p>19 that's why I believe, then, when I look at</p> <p>20 the rest of the data that fits, that it fits</p> <p>21 the definition of a nongenotoxic carcinogen</p> <p>22 by its initial mechanisms to induce cancer.</p> <p>23 Q. Okay. And if talc is, in fact,</p> <p>24 a nongenotoxic carcinogen, it would suggest</p> <p>25 that there is likely a threshold dose below</p> |

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| <p>1 which it does not have a carcinogenic effect, 2 correct? 3 MS. PARFITT: Objection. 4 THE WITNESS: It is possible, 5 and that's the problem. In order to 6 fully assess that, you would have to 7 have the data to prove it. 8 But that's the assumption. You 9 assume with nongenotoxic carcinogens 10 that you could identify a level where 11 you wouldn't turn on that indirect 12 mechanism. So that -- yes, that is 13 true. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. And you have not been able to 16 identify, nor can you point to, scientific 17 literature that identifies a threshold -- a 18 threshold dose for talc with respect to its 19 carcinogenic potential for ovarian cancer, 20 correct? 21 A. Not a specific dose, but I 22 think that's why I mentioned to you -- and 23 I -- I think that's why Canada, when you look 24 at their document, they talk about 25 discouraging routine use generally. So it's</p> | <p>1 what they've done, but is it possible 2 that they would do it? Any regulatory 3 agency, it's possible they could do 4 it, yes. 5 QUESTIONS BY MS. BRANSCOME: 6 Q. Do you have any information 7 with respect to Health Canada's 8 decision-making, other than what you have 9 read on the face of the documents? 10 A. That is all I have to look at 11 is what is provided on the website. 12 Q. Okay. And so the statement 13 that you think Health Canada was suggesting a 14 dose threshold by their statement of 15 discouraging routine use, you're basing that 16 entirely on what you read on the piece of 17 paper, correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: Well, that's what 20 they state. So, yes, I'm -- I am 21 telling you what I see on their 22 website. If that's what you're asking 23 me, yes, that is true. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. Okay. Can you point me --</p> |
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| <p>1 the issue of what -- single use of a body 2 powder or an occasional use is a different 3 risk assessment than routine use. 4 So if you want to talk about 5 thresholds that way, that's very imprecise, 6 but you could do that. You can talk about 7 whether or not there -- I do believe there's 8 a different risk profile for one or two uses 9 of talc body powder versus a risk profile of 10 somebody who uses it routinely, because I 11 think that fits that threshold definition. 12 It's the idea that you have limited 13 availability for enough particles to migrate 14 to lead to the tissue toxicity that it cannot 15 be recovered from or repair. 16 Q. You're familiar with the 17 concept of the precautionary principle, 18 correct? 19 A. Yes. 20 Q. All right. And you understand 21 that Health Canada may have made 22 recommendations with respect to product usage 23 that are purely precautionary, correct? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I disagree that's</p> | <p>1 well, do you discuss -- have you looked at, 2 as part of your opinion specifically in the 3 MDL, the studies exploring a potential link 4 between asbestos and ovarian cancer? Just 5 asbestos. 6 A. Some of the studies, yes, but I 7 have not -- I have not done a separate risk 8 assessment just for asbestos by itself, 9 because I have not assumed that there is 10 asbestos-only exposure. 11 Does that make sense? 12 But I do cite -- for example, I 13 cite to some of the early literature on -- so 14 this -- I guess where this opinion comes in 15 is on hazard and warning. So in the warnings 16 I talk about when it was known that asbestos 17 was linked with cancer, because the warning 18 standard is not causation proven but the 19 identification of the potential. And so that 20 is in my report on warnings, but that is not 21 within my discussion of the weight of the 22 evidence for risk assessment of the talc 23 product. 24 Q. Okay. 25 A. Does that make sense?</p> |

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| <p>1 Q. Uh-huh.</p> <p>2 For example, have you rendered</p> <p>3 an opinion about what dose of asbestos</p> <p>4 exposure would be necessary to cause ovarian</p> <p>5 cancer in an individual?</p> <p>6 A. No, I have not formed that</p> <p>7 opinion at this time.</p> <p>8 Q. Okay. Do you have an opinion</p> <p>9 about the background level of asbestos to</p> <p>10 which individuals are exposed with no</p> <p>11 increased risk of any type of cancer?</p> <p>12 A. No, I do not have an opinion.</p> <p>13 I do believe others do, but I do not.</p> <p>14 Q. Okay. You may have been asked</p> <p>15 some of these questions before, but I will</p> <p>16 keep them brief.</p> <p>17 Have you ever published any</p> <p>18 articles that state that talc causes ovarian</p> <p>19 cancer?</p> <p>20 A. No, I have not.</p> <p>21 Q. Have you ever publicly</p> <p>22 expressed the opinion that talc increases the</p> <p>23 risk of ovarian cancer outside of literature?</p> <p>24 A. No. My work has been in the --</p> <p>25 in the courtroom.</p> | <p>1 not classified any of the heavy metals that</p> <p>2 you've identified in your MDL report as</p> <p>3 carcinogenic to the ovary?</p> <p>4 A. So the answer is I'd have to</p> <p>5 look. I don't recall that, but I'd have to</p> <p>6 look to confirm.</p> <p>7 Q. Okay.</p> <p>8 A. That's the answer I believe I</p> <p>9 gave a few minutes ago, yes.</p> <p>10 Q. So if I look at the IARC</p> <p>11 website, then I can confirm whether or not</p> <p>12 they have identified any of those as</p> <p>13 carcinogenic to the ovary?</p> <p>14 A. Not so much the web -- well,</p> <p>15 the website or the actual documents. I think</p> <p>16 I would actually point you to the actual</p> <p>17 monograph --</p> <p>18 Q. To the monograph.</p> <p>19 A. -- because there may be</p> <p>20 evidence in there of ovarian cancer as being</p> <p>21 seen in studies. And I'd have to go look.</p> <p>22 Q. Okay. That was not part of</p> <p>23 your consideration here, correct?</p> <p>24 A. So ovarian cancer is part of my</p> <p>25 consideration, but I didn't -- in this part</p> |
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| <p>1 MS. BRANSCOME: I think we can</p> <p>2 take a break.</p> <p>3 VIDEOGRAPHER: We are going off</p> <p>4 the record at 2:57 p.m.</p> <p>5 (Off the record at 2:57 p.m.)</p> <p>6 VIDEOGRAPHER: We are back on</p> <p>7 the record at 3:13 p.m.</p> <p>8 MS. BRANSCOME: Dr. Plunkett, I</p> <p>9 have no more questions for you on</p> <p>10 behalf of Johnson & Johnson, subject</p> <p>11 to your counsel doing a direct of any</p> <p>12 kind.</p> <p>13 THE WITNESS: Sure. Thank you.</p> <p>14 EXAMINATION</p> <p>15 QUESTIONS BY MS. BOCKUS:</p> <p>16 Q. Good afternoon, Dr. Plunkett.</p> <p>17 You and I have met before. My name is Jane</p> <p>18 Bockus, and as you know, I represent Imerys</p> <p>19 in this case.</p> <p>20 A. Yes.</p> <p>21 Q. Correct?</p> <p>22 I want to go back to just touch</p> <p>23 briefly on a couple of issues that have</p> <p>24 already been addressed.</p> <p>25 Would you agree that IARC has</p> | <p>1 of my evaluation I'm trying to -- trying to</p> <p>2 describe these metals. And this is really</p> <p>3 about mechanism of biologic plausibility and</p> <p>4 the fact that these two things can go</p> <p>5 together, and then the concept of additivity</p> <p>6 is they're on hazard. The idea if you have a</p> <p>7 cancer hazard generally and you have similar</p> <p>8 mode of action, regardless of the tissue, you</p> <p>9 would be expected to have a potential</p> <p>10 additive effect when you do a risk</p> <p>11 assessment.</p> <p>12 So that's my use of that data,</p> <p>13 which is why I didn't do a separate ovarian</p> <p>14 cancer assessment for each of the each</p> <p>15 constituents but just on powder.</p> <p>16 Q. And you discuss that topic on</p> <p>17 page 47, paragraph 68, of your report,</p> <p>18 correct, the -- whether there's an additive</p> <p>19 effect?</p> <p>20 And you cite to Casarett and</p> <p>21 Doull. I don't know if I'm pronouncing those</p> <p>22 names correctly.</p> <p>23 A. I'm sorry, on what page?</p> <p>24 Q. I'm on page 47, paragraph 68.</p> <p>25 A. Okay. Sorry. I should know</p> |

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| <p>1 where it is, but...</p> <p>2 Okay. I'm there, yes. Okay.</p> <p>3 Yes, I do cite to a chapter in</p> <p>4 Casarett and Doull, yes.</p> <p>5 Q. Okay. And Casarett and Doull</p> <p>6 is a resource that you cite to for a couple</p> <p>7 of different toxicological principles that</p> <p>8 you discuss in your -- in your report,</p> <p>9 correct?</p> <p>10 A. Yes, because it's one of the</p> <p>11 most well-recognized textbooks that is used</p> <p>12 across different either universities or</p> <p>13 schools or even in regulatory agencies.</p> <p>14 I would also say I cite EPA</p> <p>15 2000 there. I'm not citing just Casarett,</p> <p>16 but I am citing Casarett as well as an EPA</p> <p>17 guidance document.</p> <p>18 Q. In Casarett and Doull, do they</p> <p>19 actually discuss talcum powder in Chapter 2,</p> <p>20 or is it more just the concept of the</p> <p>21 potential of the effects when you have two</p> <p>22 different chemicals that you're exposed to at</p> <p>23 once or three or four?</p> <p>24 A. It's the latter. It's the --</p> <p>25 because you'll notice the title is</p> | <p>1 a genetically susceptible mouse study</p> <p>2 to hurry the process along to look at,</p> <p>3 but you might not be able to do it</p> <p>4 through perineal exposure. You might</p> <p>5 have to do it through another route</p> <p>6 such as either inhalation or maybe</p> <p>7 even you could -- you could look at it</p> <p>8 through intraperitoneal injections,</p> <p>9 for example.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. Well, and what the textbook</p> <p>12 talks about is the fact that you need to</p> <p>13 study it to find out whether the effects are</p> <p>14 additive, whether the effects are something</p> <p>15 that multiply the risk, you know, so that the</p> <p>16 two together are greater than either one</p> <p>17 alone, or do the effects offset each other</p> <p>18 and reduce the risk, correct?</p> <p>19 A. That is discussed there --</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: -- which is why</p> <p>22 I've cited the EPA document. Because</p> <p>23 the EPA document addresses the issue</p> <p>24 of mixtures, and this is the issue of</p> <p>25 mode of action. If you have chemicals</p> |
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| <p>1 "Principles of Toxicology," so it's the</p> <p>2 general chapter teaching principles for risk</p> <p>3 assessment and toxicology as used in risk</p> <p>4 assessment.</p> <p>5 Q. And whether there is an</p> <p>6 additive effect of, say, talc and nickel,</p> <p>7 that's something that an experiment could be</p> <p>8 designed to study, correct?</p> <p>9 MS. PARFITT: Objection.</p> <p>10 THE WITNESS: If you're talking</p> <p>11 generally for cancer and not worried</p> <p>12 about the issue of ovarian cancer, if</p> <p>13 you're talking about cancer, like</p> <p>14 doing an inhalation experiment to look</p> <p>15 what happens to the lung, that you</p> <p>16 could do.</p> <p>17 The problem with the animal</p> <p>18 studies and ovarian cancer due to</p> <p>19 perineal exposure is it's very</p> <p>20 difficult to understand how you design</p> <p>21 a study to expose the animals that way</p> <p>22 reliably in the way that humans are</p> <p>23 exposed.</p> <p>24 But generally you could</p> <p>25 study -- you might even be able to do</p> | <p>1 that you're looking at on the issue of</p> <p>2 additivity or no effect, you will --</p> <p>3 you look at that issue of how they're</p> <p>4 affecting the tissue and underlying</p> <p>5 mechanism.</p> <p>6 But the only way to look at the</p> <p>7 magnitude absolutely of how the risk</p> <p>8 would change is by doing an</p> <p>9 experiment. That is true.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. And to your knowledge, that</p> <p>12 experiment has never been done; is that</p> <p>13 correct?</p> <p>14 A. I can't guarantee that it's</p> <p>15 only been done for nickel and talc alone, but</p> <p>16 I would -- I would state that based on --</p> <p>17 there are studies out there that have been</p> <p>18 done where they've used the body powder that</p> <p>19 we know have metals -- a variety of things</p> <p>20 within it that are not just platy talc, but</p> <p>21 those experiments are that kind of data.</p> <p>22 But as far as gathering</p> <p>23 dose-response information or teasing out</p> <p>24 individual components, that is not available.</p> <p>25 Q. Do you agree that dose response</p> |

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| <p>1 is the fundamental principle of toxicology</p> <p>2 that underpins the effects that chemicals can</p> <p>3 have on living organisms?</p> <p>4 A. When you're talking general</p> <p>5 toxicology, yes, I think it's talked about in</p> <p>6 the textbook.</p> <p>7 Q. And you agree that it is the</p> <p>8 dose of the chemical and the pattern of</p> <p>9 exposure that determines whether a chemical</p> <p>10 produces an adverse effect on an organism,</p> <p>11 not simply the presence of the chemical?</p> <p>12 A. For a typical dose-response</p> <p>13 relationship for non -- for nongenotoxic</p> <p>14 events, absolutely, I would agree that is</p> <p>15 probably true. And I don't mean nongeno --</p> <p>16 noncancer events.</p> <p>17 In the issue of cancer biology,</p> <p>18 some of those issues don't hold all the time.</p> <p>19 In other words, there are certain chemicals</p> <p>20 and certain ways of looking at cancer risk</p> <p>21 assessment where you can't assume where the</p> <p>22 threshold is or identify what a safe dose</p> <p>23 would be. But certainly I agree on the issue</p> <p>24 of noncancer risk assessment generally, or</p> <p>25 general end points of toxicity, that is true.</p> | <p>1 A. That is true with the exception</p> <p>2 of Parmley and Woodruff, which addresses this</p> <p>3 issue of --</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: Talks about the</p> <p>6 issue of exposure from the outside to</p> <p>7 the inside.</p> <p>8 But the data that is collected</p> <p>9 with the different studies they have</p> <p>10 deposited at some point -- at some</p> <p>11 position within the vagina, that is</p> <p>12 true.</p> <p>13 QUESTIONS BY MS. BOCKUS:</p> <p>14 Q. And that is not how talc is</p> <p>15 deposited in women who use it regularly in</p> <p>16 their daily routine, correct?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 Misstates the evidence.</p> <p>19 THE WITNESS: So I would say</p> <p>20 that depends on what women are doing.</p> <p>21 Perineal application, for example,</p> <p>22 application on the underwear, can lead</p> <p>23 to contact of the vaginal opening</p> <p>24 depending on the woman.</p> <p>25 For example, a woman who has</p> |
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| <p>1 Q. And again, do you agree that in</p> <p>2 general toxicology the effects that might be</p> <p>3 reported at high doses will not occur at</p> <p>4 lower doses if the concentration at the site</p> <p>5 of action falls below the threshold for</p> <p>6 toxicity?</p> <p>7 A. Yes, that could -- that could</p> <p>8 be possible, yes.</p> <p>9 Q. And do you agree that</p> <p>10 evidence-based toxicology and epidemiology</p> <p>11 dictates that the dose of the chemical is the</p> <p>12 critical factor when examining the risk posed</p> <p>13 by a chemical, not just its presence even in</p> <p>14 the human body?</p> <p>15 A. I would say that's generally</p> <p>16 true, yes, which is why I have attempted to</p> <p>17 look at the dose-response relationship as</p> <p>18 well as the prevalence of the contact.</p> <p>19 Q. And with regard to the human</p> <p>20 studies that you cite, would you agree that</p> <p>21 none of the studies that you cite in your</p> <p>22 report that have to do with migration of</p> <p>23 particles within the genital tract of the</p> <p>24 female involve applications to the perineum</p> <p>25 or outside of the genital tract?</p> | <p>1 a -- had many children has a tract</p> <p>2 that is stretched. There, indeed, you</p> <p>3 can have more direct contact than you</p> <p>4 can with a very tight -- so I would</p> <p>5 say it depends on the woman and it</p> <p>6 depends on the situation.</p> <p>7 But I do think it's generally</p> <p>8 accepted, based on my review of the</p> <p>9 literature, that there is the</p> <p>10 opportunity for exposure internally</p> <p>11 from perineal application.</p> <p>12 QUESTIONS BY MS. BOCKUS:</p> <p>13 Q. And if I understand what you</p> <p>14 testified to earlier today and yesterday, you</p> <p>15 don't have any data that would advise on --</p> <p>16 out of the talc that is deposited in the</p> <p>17 underwear, what percentage of it makes it</p> <p>18 into the reproductive tract?</p> <p>19 A. That's the data that's missing,</p> <p>20 that is true. And unfortunately, no one has</p> <p>21 done a study. It would be -- if there was a</p> <p>22 way to do that, it would be interesting to do</p> <p>23 that. I just don't see how you design that</p> <p>24 study, especially knowing the hazard of talc</p> <p>25 at this point. I think that would be a</p> |

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| <p>1 difficult study to get approval for.</p> <p>2 Q. And do you have an opinion as</p> <p>3 to whether it is even correct that each day</p> <p>4 that a woman uses talc in her underwear, that</p> <p>5 some of the talc makes its way to the ovary?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: Have I -- can I</p> <p>8 quantify that?</p> <p>9 No, I haven't quantified it. I</p> <p>10 think I got asked that earlier. I</p> <p>11 can't quantify the amount that gets</p> <p>12 there. Or, I'm sorry, I may have</p> <p>13 misheard the start of your question.</p> <p>14 I apologize.</p> <p>15 QUESTIONS BY MS. BOCKUS:</p> <p>16 Q. Yeah, I'm really asking: Do</p> <p>17 you have an opinion as to whether it happens</p> <p>18 every single time a woman applies talc to her</p> <p>19 perineal area? Does some of that talc make</p> <p>20 it to her ovary?</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: I don't think I</p> <p>24 stated it quite that way, but</p> <p>25 certainly I think the opportunity is</p> | <p>1 migration occurs every day, once a week, once</p> <p>2 a month?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I haven't</p> <p>5 formulated my point -- my opinion</p> <p>6 quite that way; however, I do believe</p> <p>7 that it is something that is going to</p> <p>8 happen routinely with exposure. I do</p> <p>9 believe that migration is something</p> <p>10 that is going on routinely with</p> <p>11 application.</p> <p>12 So with applications, I do</p> <p>13 believe that that is, but I can't tell</p> <p>14 you that this amount has migrated on</p> <p>15 this particular day with this</p> <p>16 particular application, no. That --</p> <p>17 the data that we have collected is not</p> <p>18 there to allow us to do that.</p> <p>19 QUESTIONS BY MS. BOCKUS:</p> <p>20 Q. How do you define the word</p> <p>21 "routinely" as you're using it in that</p> <p>22 answer?</p> <p>23 A. So that would be the idea of</p> <p>24 repeated exposures, you know, within a week,</p> <p>25 within a month, within a year. So not --</p> |
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| <p>1 there with every application. And of</p> <p>2 course it would depend upon the amount</p> <p>3 of time that the contact may be in</p> <p>4 place. But the opportunity is there.</p> <p>5 So, for example, if you applied</p> <p>6 it to your underwear and 30 minutes</p> <p>7 later you go to the bathroom, it's</p> <p>8 very possible that you will have wiped</p> <p>9 away, and so that that application may</p> <p>10 have taken an opportunity away. But I</p> <p>11 do believe that the opportunity is</p> <p>12 there based on the literature I have</p> <p>13 seen.</p> <p>14 And so I haven't formed the</p> <p>15 opinion, though, that it's absolutely</p> <p>16 every time. My opinion, I think, is</p> <p>17 based on the fact that I believe that</p> <p>18 there is data to indicate that</p> <p>19 exposure occurs, and that with</p> <p>20 routine, continual habit, sort of a</p> <p>21 habit exposure, that indeed that there</p> <p>22 was some migration that occurs.</p> <p>23 QUESTIONS BY MS. BOCKUS:</p> <p>24 Q. And is it fair to say that you</p> <p>25 don't have an opinion as to whether that</p> | <p>1 routine to me would not be -- would not be</p> <p>2 applying it once a month one month, waiting</p> <p>3 six months, doing it again, and then not</p> <p>4 doing it until the next year.</p> <p>5 Again, it's the idea -- some</p> <p>6 people may -- routine may be during the hot</p> <p>7 season of the year, they're routinely getting</p> <p>8 daily exposures when it's warm, and during</p> <p>9 the cold weather not applying. But then the</p> <p>10 next year doing -- that's a routine for them</p> <p>11 and their habits based on their pattern of</p> <p>12 exposure.</p> <p>13 Again, we know that talc, when</p> <p>14 it -- when it migrates and gets into the</p> <p>15 body, we have data to show that it is -- it</p> <p>16 is able to persist in the body. The fact</p> <p>17 that you may have not been exposed for three</p> <p>18 months because it was cold doesn't mean that</p> <p>19 you -- that that changes the fact that you're</p> <p>20 still at risk with additional exposures the</p> <p>21 next -- the next time that that habit</p> <p>22 becomes -- comes into place.</p> <p>23 So I think there's multiple</p> <p>24 exposure patterns that are possible, but when</p> <p>25 I use routine, it's something that people are</p> |

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| <p>1 doing throughout their -- a period of their</p> <p>2 life. And so it would be something that</p> <p>3 happens either on a weekly basis for a good</p> <p>4 part of the year. I haven't defined it with</p> <p>5 a particular number, though, no.</p> <p>6 Q. And my question had to do with</p> <p>7 out of the number of times a given woman --</p> <p>8 or an average woman uses talc, what</p> <p>9 percentage of the time does talc make its way</p> <p>10 into her reproductive tract?</p> <p>11 A. So I don't think that</p> <p>12 anybody -- anybody can point to a piece of</p> <p>13 data that tells you that, but, again, it's</p> <p>14 based upon the anatomy, I would expect there</p> <p>15 to be the potential each time it's applied.</p> <p>16 And on your question on</p> <p>17 routine, when I'm talking routine, I'm</p> <p>18 looking at not just frequency but also</p> <p>19 duration. So when I'm talking about dose,</p> <p>20 it's the fact that they do it on a repeated</p> <p>21 basis for a number of -- a period of years as</p> <p>22 well.</p> <p>23 That's what the data shows in</p> <p>24 the human studies. It's not something,</p> <p>25 again, that may have been done routinely for</p> | <p>1 opinion on a set number, no. I can't --</p> <p>2 can't point you a specific number.</p> <p>3 I'm not doing case-specific, so</p> <p>4 I've not looked at any of those pieces of</p> <p>5 information for any given plaintiff.</p> <p>6 Q. And I'm just trying to get the</p> <p>7 threshold.</p> <p>8 A. Uh-huh.</p> <p>9 Q. As I understand it, that is</p> <p>10 part of a toxicological evaluation, is the</p> <p>11 threshold below which there's not an issue.</p> <p>12 So I think you've said you</p> <p>13 don't know if it's less than a year, but you</p> <p>14 think it's more likely than not that it's</p> <p>15 greater than one month.</p> <p>16 MR. MEADOWS: Objection.</p> <p>17 QUESTIONS BY MS. BOCKUS:</p> <p>18 Q. Is that fair?</p> <p>19 A. No, that's not exactly what I'm</p> <p>20 saying. I'm saying we don't know the</p> <p>21 threshold. So as a result, I'm not of the</p> <p>22 opinion that it absolutely can't -- it only</p> <p>23 has to be this long.</p> <p>24 What I'm saying to you is per</p> <p>25 general principles of toxicology and based on</p> |
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| <p>1 one year, but it does appear to be something</p> <p>2 that's done more -- longer term than that.</p> <p>3 But we can't give a number. We</p> <p>4 have no threshold. We don't know exactly</p> <p>5 what that minimum number is.</p> <p>6 Q. Do you think that the minimum</p> <p>7 number is greater than a year?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: I haven't formed</p> <p>10 that opinion, no.</p> <p>11 QUESTIONS BY MS. BOCKUS:</p> <p>12 Q. Do you think it's greater than</p> <p>13 a month?</p> <p>14 MR. MEADOWS: Objection.</p> <p>15 THE WITNESS: Greater than a</p> <p>16 month?</p> <p>17 QUESTIONS BY MS. BOCKUS:</p> <p>18 Q. Yes.</p> <p>19 A. One month in their life?</p> <p>20 Q. One month in their life, where</p> <p>21 they're using it every day for a month.</p> <p>22 A. So I haven't formed that</p> <p>23 opinion at this point in time, but I'd say</p> <p>24 it's more likely to occur when you do it more</p> <p>25 than a month. But I haven't formed an</p> | <p>1 the human data that we have, it indicates</p> <p>2 that it's more frequent than just one month,</p> <p>3 but I can't tell you that it's absolutely not</p> <p>4 possible.</p> <p>5 That's where -- I do think when</p> <p>6 you're talking about those kinds of patterns,</p> <p>7 that's a case-specific issue for individuals,</p> <p>8 because I think that would have to be</p> <p>9 considered for each individual. But</p> <p>10 certainly as a toxicologist, I'm using the</p> <p>11 words "routine," "repeated," "longer</p> <p>12 duration," "chronic exposure." And when I</p> <p>13 defined "chronic" earlier, I talked about</p> <p>14 years of exposure versus just one month.</p> <p>15 That would be consistent with</p> <p>16 what I have said, yes, but I'm not -- I -- I</p> <p>17 certainly don't want to rule out that there</p> <p>18 couldn't be somebody out there that could</p> <p>19 show something different, because it may very</p> <p>20 well be that there are people that you can</p> <p>21 identify with the presence of talc in their</p> <p>22 ovaries and all of their other case-specific</p> <p>23 things that could -- could make that pattern</p> <p>24 a -- make someone be able to draw a</p> <p>25 case-specific, reliable conclusion.</p> |

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| <p>1 But that's not my role. I</p> <p>2 don't do case-specific.</p> <p>3 Q. And I am simply trying to get</p> <p>4 the parameters of your opinions with regard</p> <p>5 to the amount of talc use one would need to</p> <p>6 have before you would feel comfortable --</p> <p>7 well, that in your opinion would be</p> <p>8 sufficient to create a toxic environment.</p> <p>9 MR. MEADOWS: Objection.</p> <p>10 THE WITNESS: Well, that's a</p> <p>11 different question. So toxic</p> <p>12 environment could be with a much</p> <p>13 shorter time exposure, okay?</p> <p>14 QUESTIONS BY MS. BOCKUS:</p> <p>15 Q. Right.</p> <p>16 A. So but if you're talking</p> <p>17 about -- the opinion that I have formed has</p> <p>18 to do with an increased risk of ovarian</p> <p>19 cancer. So with that opinion, that's the</p> <p>20 description, I believe, I was giving this</p> <p>21 morning. It's the idea that the data that</p> <p>22 I've seen indicates that my opinion that</p> <p>23 perineal use of talc body powder products</p> <p>24 increases your risk for ovarian cancer above</p> <p>25 that background level that you know exists.</p> | <p>1 QUESTIONS BY MS. BOCKUS:</p> <p>2 Q. Okay. An ingredient supplier.</p> <p>3 And you agree that Imerys does</p> <p>4 not sell any products to the general public,</p> <p>5 correct?</p> <p>6 MR. MEADOWS: Objection.</p> <p>7 THE WITNESS: I don't know</p> <p>8 that's definitely true, but I'm not</p> <p>9 aware that they do.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. And what Imerys supplies to</p> <p>12 Johnson & Johnson is not a finished cosmetic</p> <p>13 that is ready to be sold on the market,</p> <p>14 correct?</p> <p>15 MR. MEADOWS: Objection.</p> <p>16 MS. PARFITT: Objection.</p> <p>17 THE WITNESS: I don't know that</p> <p>18 I can answer that except in the</p> <p>19 context of Johnson & Johnson's baby</p> <p>20 powder, SHOWER TO SHOWER® and Shimmer,</p> <p>21 it's my understanding that Johnson &</p> <p>22 Johnson mixes -- has some fragrance</p> <p>23 added to the talc.</p> <p>24 I don't believe Imerys does</p> <p>25 that, but I don't know for sure.</p> |
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| <p>1 That opinion is based on data</p> <p>2 that is -- is -- the supporting data would</p> <p>3 indicate that it has to be a habit, routine,</p> <p>4 a chronic exposure. And so as a</p> <p>5 toxicologist, I've tried to put that in</p> <p>6 context.</p> <p>7 I don't know what else to tell</p> <p>8 you. That's the opinions I have formed to</p> <p>9 date.</p> <p>10 Q. A chronic -- a habit, routine,</p> <p>11 a chronic exposure for years?</p> <p>12 A. Well, chronic --</p> <p>13 MR. MEADOWS: Objection.</p> <p>14 THE WITNESS: -- is defined as</p> <p>15 years, typically, by a toxicologist,</p> <p>16 and so that's what I -- that's what I</p> <p>17 told you.</p> <p>18 QUESTIONS BY MS. BOCKUS:</p> <p>19 Q. Shifting to your regulatory</p> <p>20 opinions, you would agree that Imerys is a</p> <p>21 raw material supplier to J&J; is that</p> <p>22 correct?</p> <p>23 MR. MEADOWS: Objection.</p> <p>24 THE WITNESS: I would call them</p> <p>25 an ingredient supplier, yes.</p> | <p>1 So based on what I know -- I'm</p> <p>2 telling you what I know, and I would</p> <p>3 call them, again, an ingredient</p> <p>4 supplier, and I would call Johnson &</p> <p>5 Johnson a cosmetic manufacturer.</p> <p>6 Does that answer the question?</p> <p>7 QUESTIONS BY MS. BOCKUS:</p> <p>8 Q. It does.</p> <p>9 Would you agree that the</p> <p>10 minerals that you have identified in your</p> <p>11 report, that the documents that you have</p> <p>12 seen, would classify their -- to the extent</p> <p>13 that they are ever in the powder, that</p> <p>14 they're trace ingredients?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 MR. MEADOWS: Objection.</p> <p>17 THE WITNESS: So which</p> <p>18 ingredients are you referring to?</p> <p>19 So some of the metals, no, are</p> <p>20 not trace ingredients.</p> <p>21 Are you talking about the --</p> <p>22 are you talking about the -- like the</p> <p>23 presence of tremolite or the presence</p> <p>24 of chrysotile --</p> <p>25</p> |

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| <p>1 QUESTIONS BY MS. BOCKUS: 2 Q. No. No, I'm sorry. I'm 3 talking about the three metals that you 4 identify in your report. Those are trace 5 elements that are -- that are sometimes 6 detected in the studies of the -- of the 7 talc. 8 MR. MEADOWS: Objection. 9 THE WITNESS: It's not how I 10 would say it. I would say they're 11 heavy metal components that are 12 naturally occurring within the product 13 that are sometimes -- sometimes 14 detectable at levels that are reported 15 as trace based on the detection limit 16 within the analysis, but at other 17 times they're not listed as trace. 18 They're actually listed with a 19 specific amount. 20 So that's what -- how I would 21 define what I call trace. Usually 22 that's how it will be reported in the 23 lab, trace, which means below the 24 limit of quantification, but it's 25 there. You're detecting it.</p> | <p>1 QUESTIONS BY MS. BOCKUS: 2 Q. Have you seen any studies where 3 women's blood has reflected the presence of 4 nickel or cobalt or chromium? 5 MR. MEADOWS: Objection. 6 QUESTIONS BY MS. BOCKUS: 7 Q. Who are parts of these 8 studies -- these ovarian cancer studies? 9 MR. MEADOWS: Objection. 10 THE WITNESS: The 11 epidemiological literature you're 12 asking me? 13 QUESTIONS BY MS. BOCKUS: 14 Q. Yes, ma'am. 15 A. It's possible in the Nurses' 16 Health Study that we can go to that, because 17 I know they do collect some heavy metal 18 levels. I've done that for other clients on 19 other issues. 20 Most of the others, I doubt 21 that we have heavy metal levels in blood. 22 But certainly there are levels of heavy metal 23 in blood, especially things like lead, for 24 example, that we have very limited capacity 25 to eliminate.</p> |
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| <p>1 I would agree that -- that 2 there are other descriptions of heavy 3 metals in the heavy metal literature 4 that talk about trace amounts being 5 found in -- naturally occurring in 6 food, for example, and I agree that 7 that does occur. But in the case of 8 this product, we actually have 9 often -- we actually have a -- a limit 10 that is set for acceptability in the 11 specification. 12 And so I would think it's more 13 proper to call it a level of the heavy 14 metal that is allowable by the purity 15 specifications set by the product. 16 And sometimes those levels may be 17 above, and most of the times those 18 levels are below, which is why it's 19 cleared. Because I've seen some 20 analyses where different products may 21 have been, I guess, turned away or 22 considered not acceptable based on the 23 analysis of certain types of minerals 24 or metals. 25</p> | <p>1 So whether or not you carry 2 around a significant body burden of a heavy 3 metal in your blood is somewhat driven by the 4 exposure pattern you get. It's something 5 that's commonly -- or can you excrete it 6 quickly or not. So... 7 Q. And are you familiar with any 8 studies that have suggested that the use of 9 body powders leads to a heavy burden of 10 nickel, chromium or cobalt in the blood? 11 A. So I have not seen such 12 analysis done, no, I have not. 13 Q. In paragraph 67 of your report, 14 which is on page 46 -- I'm sorry, on -- oh, 15 I'm sorry. Paragraph 64, I apologize. 16 A. No. No, that's fine. 17 Q. It's on page 44. 18 You cite to two abstracts -- 19 A. Yes. 20 Q. -- one by Fletcher and one by 21 Fletcher and Saed. 22 Do you consider these abstracts 23 to be reliable sources of data? 24 A. They're not as reliable at all 25 as a peer-reviewed article. So there's a</p> |

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| <p>1 difference in the weight you give an 2 abstract, absolutely. 3 However, knowing the papers 4 that Dr. Saed has actually published in the 5 peer-reviewed literature, I have -- I have 6 mentioned them in here because I do believe 7 that they are -- they are pieces of 8 information that are highly relevant to some 9 of the issues raised in other cellular 10 studies, and so that's why they're here. But 11 certainly I do not give them the same weight 12 as in my assessment of overall risk. 13 And I would say that I had the 14 same opinions on risk before I had these 15 studies. Because in my original reports, 16 obviously, I have gone further than risk and 17 talked about cause, and I didn't have the 18 Fletcher studies. 19 The Fletcher studies are more 20 on the issue of biologic plausibility and 21 mechanism versus being important 22 underpinnings, for example, for a hazard 23 assessment. 24 Q. Is there any way that someone 25 reading your report could tell that you</p> | <p>1 A. I attempted to do that. I 2 can't tell that you there isn't something in 3 here I've missed. But, yes, I read this 4 report six or seven times before I finalized 5 it, trying to make sure that the language I 6 was using was an accurate reflection of the 7 opinion I'm expressing. 8 But it's possible, if you want 9 to point to something that you want to ask me 10 about, I can tell you whether or not that was 11 something that I would change. 12 Q. So on page 77, paragraph 118 in 13 the middle of it, you say, "Based on the 14 knowledge available by the 1950s, talc body 15 powders manufactured and sold by Imerys and 16 Johnson & Johnson." 17 And that's the question that I 18 have for you. 19 A. I see what you're saying. 20 Q. Was Imerys selling anything to 21 Johnson & Johnson in the 1950s? 22 MR. MEADOWS: Objection. 23 THE WITNESS: I'm thinking. 24 It's possible they did not. That may 25 be true.</p> |
| Page 315 | Page 317 |
| <p>1 attribute less weight to the abstracts by 2 Saed and Fletcher just by reading your 3 report? 4 MR. MEADOWS: Objection. 5 THE WITNESS: I don't know if 6 they could or not. Hopefully they 7 would based upon where they appear in 8 the report. They're not cited a lot 9 of other places, but they certainly 10 are cited. 11 So that's why I'm here today, 12 though. You're asking me these 13 questions; I'm telling you. That's 14 how I look at these studies. That's 15 all I can say. 16 I haven't -- I haven't, 17 certainly, as I've told you, given 18 things numerical weight throughout my 19 report. 20 QUESTIONS BY MS. BOCKUS: 21 Q. Looking at paragraph 118... 22 Well, when you were preparing 23 your report, were you careful with the 24 language that you used in it to be precise 25 and accurate?</p> | <p>1 QUESTIONS BY MS. BOCKUS: 2 Q. Well, and actually -- 3 A. You know what? When I wrote 4 this sentence, I assumed that they did, but 5 if that is not true, then certainly this 6 sentence should be just Johnson & Johnson. 7 Q. Well, earlier in your report, 8 in a footnote you indicate that Imerys began 9 supplying talc to Johnson & Johnson in 1989 10 or the late 1980s. 11 Do you remember making that 12 notation? 13 A. So let me look. So if that's 14 an inconsistency, then that should change. 15 Let me look. 16 Q. And that's all I want to know, 17 if it's an inconsistency, should it change. 18 A. If it is an inconsistency -- 19 certainly if Imerys was not selling talc to 20 Johnson & Johnson in 19 -- the 1950s, then -- 21 then certainly Johnson & Johnson's products 22 would not -- would not be affected by Imerys' 23 activity. 24 However, if Imerys is selling 25 talc to anyone that makes a consumer product</p> |

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|---|--|
| <p>1 in the 1950s, then -- or a precursor company</p> <p>2 to Imerys is making talc that's selling for</p> <p>3 body powder to somebody other than Johnson &</p> <p>4 Johnson, then that opinion would still hold.</p> <p>5 So -- but I certainly agree, I</p> <p>6 think I -- you're right, I think I have a</p> <p>7 statement about the link between the two in</p> <p>8 '89. So in that case, then certainly the --</p> <p>9 the link here would be related to Johnson &</p> <p>10 Johnson's products.</p> <p>11 Q. Okay. Yeah.</p> <p>12 A. Whether or not -- if they</p> <p>13 weren't sourced from Imerys, then that's a</p> <p>14 separate duty on a product, not this product.</p> <p>15 Q. If you look on the bottom of</p> <p>16 page 7, I think you'll see the footnote I was</p> <p>17 referencing.</p> <p>18 And with regard to your last</p> <p>19 answer, you don't have any information as to</p> <p>20 whether Imerys existed and, if it did,</p> <p>21 what -- who its customers were in 1950s,</p> <p>22 correct?</p> <p>23 A. I don't believe I do, no.</p> <p>24 MS. BOCKUS: I think that's all</p> <p>25 that I have. Thank you.</p> | <p>1 complete assessment the way I did, then I</p> <p>2 would agree that other people could come to a</p> <p>3 different conclusion, absolutely.</p> <p>4 So I think it depends what you</p> <p>5 mean by "reasonable scientist." But I would</p> <p>6 agree that individuals can look at the same</p> <p>7 body of data and, based on their judgment and</p> <p>8 experience, based on looking at that same</p> <p>9 body of data, could come to a different</p> <p>10 conclusion, yes. That's true.</p> <p>11 Q. You've been involved in this</p> <p>12 talc litigation for at least a couple of</p> <p>13 years, right?</p> <p>14 A. Yes.</p> <p>15 Q. And you know that various</p> <p>16 defendants have offered experts who disagree</p> <p>17 with your conclusions, right?</p> <p>18 A. Some of my conclusions, yes. I</p> <p>19 don't know that there is somebody that's in</p> <p>20 the litigation that does exactly what I do</p> <p>21 across all the opinions I've expressed, but,</p> <p>22 yes, certain parts of my opinions there are</p> <p>23 other experts I'm aware of, yes.</p> <p>24 Q. Well, they -- you're aware that</p> <p>25 there are defense experts who disagree with</p> |
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| <p>1 MR. LOCKE: I've got a few</p> <p>2 questions.</p> <p>3 EXAMINATION</p> <p>4 QUESTIONS BY MR. LOCKE:</p> <p>5 Q. Doctor, my name's Tom Locke. I</p> <p>6 represent the Personal Care Products Council.</p> <p>7 We met a couple of times before, I think.</p> <p>8 A. I apologize, I don't recall</p> <p>9 your name at least. The face looked</p> <p>10 familiar, though. I apologize.</p> <p>11 Q. I try to maintain a low</p> <p>12 profile.</p> <p>13 I have relatively few</p> <p>14 questions. I wanted to ask you overall about</p> <p>15 your opinion.</p> <p>16 Would you agree that reasonable</p> <p>17 scientists can disagree with your opinion</p> <p>18 that talc increases the risk of ovarian</p> <p>19 cancer?</p> <p>20 A. I'd say I wouldn't say it quite</p> <p>21 that way. I'd say that I agree that</p> <p>22 scientists can disagree on conclusions they</p> <p>23 draw, depending on the -- depending on the</p> <p>24 way that they have assessed.</p> <p>25 So certainly based on a</p> | <p>1 your opinion that talc increases the risk of</p> <p>2 ovarian cancer; is that correct?</p> <p>3 A. Yes, I -- I am aware of that</p> <p>4 fact.</p> <p>5 Q. And in your review of the</p> <p>6 records that go back or the scientific</p> <p>7 materials that go back 35 years or more,</p> <p>8 you've seen that there's disagreement</p> <p>9 regarding that issue; is that correct?</p> <p>10 A. So what documents are you</p> <p>11 referring to? Are you asking me about a</p> <p>12 specific -- just the published medical</p> <p>13 literature? Are you asking about documents</p> <p>14 like internal company documents, reviews by</p> <p>15 others? What are you asking me about?</p> <p>16 Q. Well, let's focus on the</p> <p>17 published medical literature.</p> <p>18 There are scientists who have</p> <p>19 disagreed with your opinion; is that correct?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: I'm not aware of</p> <p>22 a paper in the published medical</p> <p>23 literature that has done the exact</p> <p>24 assessment I have done.</p> <p>25 So I am aware of the fact,</p> |

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|---|--|
| <p>1 however, that there are individual</p> <p>2 papers by scientists that, for</p> <p>3 example, have concluded that there is</p> <p>4 no association between exposure to</p> <p>5 talc perineally and ovarian cancer,</p> <p>6 yes. Individual papers, I am aware of</p> <p>7 that, but that's different than what I</p> <p>8 have done.</p> <p>9 QUESTIONS BY MR. LOCKE:</p> <p>10 Q. Let me just ask you about what</p> <p>11 you were requested to do on behalf of</p> <p>12 plaintiff's counsel.</p> <p>13 Plaintiff's counsel asked you</p> <p>14 to provide opinions related to the human</p> <p>15 health hazards posed by exposure to talcum</p> <p>16 powder products and how those hazards relate</p> <p>17 to the regulatory requirements for marketing</p> <p>18 cosmetic ingredients and cosmetic products in</p> <p>19 the United States; is that correct?</p> <p>20 MR. MEADOWS: Objection.</p> <p>21 THE WITNESS: I didn't write</p> <p>22 that, but that sounds like an accurate</p> <p>23 reflection of what -- what we -- what</p> <p>24 I have done at least in parts of my</p> <p>25 report, yes.</p> | <p>1 what I've been doing in the litigation.</p> <p>2 Q. Okay. As to that second</p> <p>3 bucket, the US regulatory requirements for</p> <p>4 marketing cosmetic ingredients and products,</p> <p>5 that's not relevant to the scientific</p> <p>6 question whether talc may cause ovarian</p> <p>7 cancer; am I right?</p> <p>8 A. No. I disagree with that based</p> <p>9 on the fact that a company that markets a</p> <p>10 cosmetic product is required to do a safety</p> <p>11 assessment. And if in that safety assessment</p> <p>12 issues relate to cancer or ovarian cancer and</p> <p>13 the use of talc, then those two things are</p> <p>14 related.</p> <p>15 But I would agree that -- that</p> <p>16 doing a risk assessment like I've done is a</p> <p>17 separate issue from doing a safety assessment</p> <p>18 for a product, because there's actually even</p> <p>19 a lesser standard for an issue of looking at</p> <p>20 a safety assessment for a product versus</p> <p>21 actually forming the opinion that there is an</p> <p>22 increased risk of cancer with exposure to</p> <p>23 talc.</p> <p>24 Q. Now, did IARC in 2006, did it</p> <p>25 look at the US regulatory process in</p> |
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| <p>1 QUESTIONS BY MR. LOCKE:</p> <p>2 Q. Well, if you look at your</p> <p>3 report, I think you go to part where you were</p> <p>4 asked to provide -- and I just pulled it from</p> <p>5 what you said.</p> <p>6 A. So I did write it, I apologize.</p> <p>7 It didn't sound like me.</p> <p>8 Q. It started with "to provide</p> <p>9 opinions related to the human health hazards"</p> <p>10 and so forth, so I just wanted to make sure</p> <p>11 we're clear on that.</p> <p>12 A. Sure.</p> <p>13 Q. So does that sound right in</p> <p>14 terms of what you were asked to do?</p> <p>15 A. I said I -- certainly those are</p> <p>16 the kinds of things that I was definitely</p> <p>17 asked to do. I was asked to do two basic --</p> <p>18 two basic things, which was having to do with</p> <p>19 toxicology and risk assessment, and then a</p> <p>20 separate issue related to regulatory</p> <p>21 concerns.</p> <p>22 So, yes, those are the two</p> <p>23 basic, I guess, buckets of information and</p> <p>24 documents that I reviewed and opinions I've</p> <p>25 expressed, and I think that's consistent with</p> | <p>1 considering whether talc may cause ovarian</p> <p>2 cancer?</p> <p>3 MR. MEADOWS: Objection.</p> <p>4 THE WITNESS: I don't think I</p> <p>5 understand what you mean. It's not a</p> <p>6 US regulatory process, no, if that's</p> <p>7 what you're asking me.</p> <p>8 They have a -- they have a</p> <p>9 discussion of what the products are,</p> <p>10 which is part of the way they're sold.</p> <p>11 But I don't think they're discussing</p> <p>12 the duty of a company under the</p> <p>13 regulatory process, no, that's a</p> <p>14 separate issue.</p> <p>15 QUESTIONS BY MR. LOCKE:</p> <p>16 Q. So their analysis of whether</p> <p>17 talc may cause ovarian cancer, that's</p> <p>18 different than the analysis of whether a</p> <p>19 company may have a duty, whatever that duty</p> <p>20 may be?</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 THE WITNESS: It's a different</p> <p>23 process, absolutely. IARC is a</p> <p>24 separate, independent body that does</p> <p>25 an assessment looking at the issue of</p> |

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| <p>1 cancer hazard and looking at whether 2 or not there is sufficient evidence to 3 categorize that hazard, whereas a duty 4 of a company under the regulatory 5 situation is broader than just cancer 6 hazard; it's a whole different thing. 7 It's what you do internally before you 8 market a product. Totally different. 9 And so certainly when I -- 10 that's why I have separate sections in 11 my report, and that's why I even 12 have -- I've had discussions about the 13 difference between the regulatory 14 standard for warning versus the 15 assessment of risk that may be 16 required in order to start to produce 17 a -- identify a association or an 18 increased risk or even if you did a 19 causation analysis. Totally different 20 type of exercise. 21 QUESTIONS BY MR. LOCKE: 22 Q. Do you first, in that exercise, 23 look at the scientific issue of whether talc 24 may cause ovarian cancer? 25 A. Are you asking me in either of</p> | <p>1 this is a different assessment and 2 different standard. It's a much lower 3 standard on cosmetics for what needs 4 to be done as far as warning. 5 Now, when a company comes and 6 initiates a safety assessment on their 7 product, before they even think about 8 what am I going to warn, they should 9 be doing a comprehensive assessment of 10 safety based on what's available 11 publicly, knowing what others have 12 reported and then what data they've 13 collected. 14 If they don't have data at all 15 on the safety of the product, then the 16 product has to say that. We don't 17 know. We do not know if this product 18 is safe. And that's one of the things 19 that is allowed under FDA -- under FDA 20 regulations as well. 21 But essentially some -- some 22 assessment must be done to understand 23 from the perspective of the company 24 that this product is safe for 25 consumers to use as -- under the</p> |
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| <p>1 these exercises? 2 Q. Well, let's say when you're 3 getting to -- you mentioned the duty to warn. 4 So if you're looking at the duty to warn, do 5 you first have to look at does talc cause 6 ovarian cancer? 7 MR. MEADOWS: Objection. 8 THE WITNESS: That's not the 9 question you asked. No. I would 10 argue, based on the regulations, if 11 you look at the standard, the question 12 is, is there evidence to indicate that 13 there is a chance, there is a 14 potential -- not that it does, but is 15 there a potential for that type of 16 hazard to be posed to consumers who 17 use the product. 18 It's a possibility versus being 19 a -- I'm taking it beyond possibility 20 when I'm doing my assessment for 21 increased risk. And I talked about 22 that this morning, and I can't 23 remember her last name. The 24 Johnson -- I apologize. But I -- with 25 Johnson & Johnson. I talked about</p> | <p>1 directions of use. 2 So in the case of this, it 3 would be a body powder being used on 4 the body surface but also perineally 5 because -- because that was an 6 exposure pattern that was understood. 7 QUESTIONS BY MR. LOCKE: 8 Q. Okay. You described two 9 different buckets. They're independent 10 assessments; is that correct? 11 MR. MEADOWS: Objection. 12 THE WITNESS: Initially that's 13 where I started, and now I'm talking 14 two different duties. There's a duty 15 to warn, but there's first a duty to 16 collect information before you market 17 it. It's your premarket safety 18 assessment. 19 QUESTIONS BY MR. LOCKE: 20 Q. Okay. I'm not actually talking 21 about the manufacturer's duty. I wanted to 22 just first address your scientific analysis. 23 That's a separate question that 24 led you to your opinion on the -- your 25 opinion that talc increases the risk of</p> |

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|---|--|
| <p>1 ovarian cancer, correct?</p> <p>2 MR. MEADOWS: Objection.</p> <p>3 THE WITNESS: Yes, that's what</p> <p>4 I described. And I thought you were</p> <p>5 talking about duty of the company, and</p> <p>6 so I apologize. I didn't mean to go</p> <p>7 off on a tangent.</p> <p>8 If you want to focus just on</p> <p>9 the risk assessment -- is that what</p> <p>10 you want to do? -- that's what I'm</p> <p>11 doing.</p> <p>12 QUESTIONS BY MR. LOCKE:</p> <p>13 Q. No, I just want to understand,</p> <p>14 those are two different things, though,</p> <p>15 right?</p> <p>16 A. Those are two different --</p> <p>17 those are two different tasks that I</p> <p>18 undertook, yes. I undertook a risk</p> <p>19 assessment task to form opinions based on</p> <p>20 what I can say about risk, and then I</p> <p>21 separately -- and I had done this earlier on</p> <p>22 the issue of warnings, looking at what do we</p> <p>23 know about the product and whether or not --</p> <p>24 and when did we know it, and what should</p> <p>25 consumers have been warned about based on the</p> | <p>1 also sort of -- that's a piece along the way</p> <p>2 to doing a causation analysis, but it's not</p> <p>3 the same.</p> <p>4 Q. Your opinion regarding the</p> <p>5 FDA's responsibilities and functions, that's</p> <p>6 not related to your opinion that talc may</p> <p>7 cause an increased risk in ovarian cancer; is</p> <p>8 that correct?</p> <p>9 MR. MEADOWS: Objection.</p> <p>10 THE WITNESS: I don't think</p> <p>11 that's true the way you're asking that</p> <p>12 question, because I don't know how you</p> <p>13 divorce the fact that as a -- in a</p> <p>14 regulatory assessment, if I identify</p> <p>15 cancer hazard, I have identified a</p> <p>16 duty to warn. That's certainly</p> <p>17 something that should be warned about</p> <p>18 when I understand that there's not</p> <p>19 only the potential, but I believe</p> <p>20 there's an increased risk.</p> <p>21 But I would agree with you that</p> <p>22 in my report, I'm laying out for you</p> <p>23 even different bodies of information</p> <p>24 that -- as I step through it.</p> <p>25 Does that make sense to you?</p> |
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| <p>1 safety information that was available over</p> <p>2 time.</p> <p>3 Q. The risk assessment task,</p> <p>4 that's what you mean by your analysis that</p> <p>5 talc increases the risk of ovarian cancer?</p> <p>6 A. That's correct.</p> <p>7 Q. You could have stopped at that,</p> <p>8 but then you performed an additional task; is</p> <p>9 that right?</p> <p>10 A. Well, actually, no, because the</p> <p>11 first task I actually started with was the</p> <p>12 regulatory task. When I first started</p> <p>13 getting involved in the litigation very --</p> <p>14 before I wrote my first report, one of the</p> <p>15 first things I was looking at was the issue</p> <p>16 of the duty of the manufacturer to provide</p> <p>17 warnings.</p> <p>18 And then after that, I expanded</p> <p>19 that role to be an inclusion as well of a</p> <p>20 causation analysis.</p> <p>21 And then now I'm not doing a</p> <p>22 full causation analysis in this litigation,</p> <p>23 but I'm using essentially some of the same</p> <p>24 information to provide you with a description</p> <p>25 of a -- a health risk assessment, which was</p> | <p>1 QUESTIONS BY MR. LOCKE:</p> <p>2 Q. Not really.</p> <p>3 A. I'm sorry.</p> <p>4 Q. I'm talking about your</p> <p>5 scientific analysis here, not your regulatory</p> <p>6 analysis.</p> <p>7 To do your scientific analysis,</p> <p>8 you looked at scientific materials, right?</p> <p>9 A. Yes, but I do the same thing</p> <p>10 for my regulatory analysis. That's why I'm</p> <p>11 confused. I -- to me they are connected.</p> <p>12 But I would agree with you, I</p> <p>13 had an analysis. Let's just talk about that,</p> <p>14 my analysis on risk assessment and my</p> <p>15 opinions that I've expressed. Those are laid</p> <p>16 out in a separate section of my report,</p> <p>17 absolutely. So we could talk about that if</p> <p>18 you'd like.</p> <p>19 Q. Well, I just want to</p> <p>20 understand, and I think I do now, that's a</p> <p>21 separate issue from your regulatory opinion?</p> <p>22 A. It's not a separate issue.</p> <p>23 That's where I'm having trouble with your</p> <p>24 language.</p> <p>25 It's a separate task because,</p> |

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| <p>1 for example, I may have only been asked, but 2 I wasn't, to just describe whether or not, as 3 a human risk assessor and toxicologist, there 4 is a hazard or a risk posed by the product, 5 and I could stop there. 6 But I was asked, based on -- 7 based on my experience working in the area of 8 regulatory toxicology but also on regulatory 9 issues for clients where I give advice, I was 10 asked to look at how does that scientific 11 information impact what the company should be 12 doing. 13 And so that's -- that's why I'm 14 saying you can't divorce them, because the 15 warning issue I'm talking about is intimately 16 tied into the human health risk assessment 17 results. 18 Q. So do you consider yourself 19 primarily here as a warning expert? 20 MR. MEADOWS: Objection. 21 THE WITNESS: I consider that 22 one of my roles, yes, absolutely. 23 It depends upon how individual 24 cases, individual attorneys, will -- 25 will ask -- decide to use me. For</p> | <p>1 But I practice in both those areas in 2 my consulting practice and in my 3 experience. 4 QUESTIONS BY MR. LOCKE: 5 Q. Let me ask you a few questions 6 about your cosmetic ingredient review 7 statements, CIR. 8 We can agree to call it that, 9 right? 10 A. Yes, that's fine. 11 Q. In parts of your report, you 12 cite the CIR as an authoritative source on 13 cosmetic ingredients; is that correct? 14 A. So where are you looking at, 15 the background information on the CIR? 16 Yes, they certainly are a 17 source of information that FDA relies upon as 18 far as assessments, yes, that's true. 19 Q. Well, and on page -- or 20 paragraph 35, page 23, you cite to the CIR 21 on, for example, chemicals purportedly in 22 cosmetics. You have a footnote there. 23 A. So -- 24 Q. I believe it's footnote 31. 25 A. Yes, I have looked at -- looked</p> |
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| <p>1 example, I have been used in one trial 2 to only talk about the toxicology. 3 Other trials, I've talked about 4 toxicology as well as regulatory 5 issues. So I think it just depends on 6 the case. 7 In the MDL, I am prepared, 8 however, to come to talk at a trial on 9 the regulatory system that guides 10 cosmetics as well as provide opinions 11 that talk about what are the hazards 12 of talc, what is the toxicology of 13 talc, what do -- how can you be 14 exposed to talc, that migration issue, 15 and then my opinions about whether or 16 not I believe that there is an 17 increased risk of ovarian cancer. 18 So I would be -- be prepared to 19 talk about both of those things. 20 That's why I said I do think I'm a 21 little different than some of the 22 other experts that you may encounter, 23 for example, in the defense side, 24 where someone may just do regulatory 25 or somebody may just do toxicology.</p> | <p>1 at the CIR as a source of information because 2 many of the chemicals, many of the 3 ingredients within the fragrance of Johnson & 4 Johnson, the only available information may 5 be found within the CIR that's publicly 6 available. 7 Q. And you rely on the report of 8 Dr. Cralley; is that correct? 9 MR. MEADOWS: Objection. 10 MS. PARFITT: Objection. 11 QUESTIONS BY MR. LOCKE: 12 Q. You reference Appendix D to 13 your report. I believe if you stay on the 14 same page you'll see that, the same 15 paragraph. 16 A. I wouldn't say I rely on the 17 report of Dr. Cralley because I form my 18 opinions independent of Dr. Cralley, but 19 certainly his -- I believe if you go to his 20 reports, his report is supportive of my 21 opinions in this area. 22 Q. Did you read his report? 23 A. I have read it now, but I did 24 not read it before I -- before I formed my 25 opinions in this particular paragraph, yes.</p> |

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| <p>1 Q. I'm a little confused because</p> <p>2 you're citing to his report.</p> <p>3 You read it or you didn't read</p> <p>4 it before you wrote this paragraph?</p> <p>5 A. I read it before I wrote the</p> <p>6 paragraph. I didn't read it before I had</p> <p>7 formed the opinion. Do you understand what</p> <p>8 I'm saying?</p> <p>9 I did my review of the irritant</p> <p>10 chemicals independently before I looked at</p> <p>11 Dr. Cralley's report. So I had formed the</p> <p>12 opinion that -- of the chemicals I had</p> <p>13 searched for that this is what I identified.</p> <p>14 And that's what this is talking about, right?</p> <p>15 I'm saying here that of the</p> <p>16 more than 100 chemicals included, over</p> <p>17 70 percent are compounds linked with some</p> <p>18 level of irritant hazard. That was done on</p> <p>19 my own.</p> <p>20 Then, if you go to look at</p> <p>21 Dr. Cralley's report, I cite it here because</p> <p>22 it's consistent. That is, his report</p> <p>23 provides support additionally for the</p> <p>24 statement I'm making.</p> <p>25 So I'm not relying on his</p> | <p>1 is no other source available.</p> <p>2 Q. Okay. In your report you state</p> <p>3 that the CIR process is administered</p> <p>4 independent of the FDA.</p> <p>5 But the FDA is on the CIR</p> <p>6 steering committee; is that correct?</p> <p>7 A. That is correct.</p> <p>8 Q. You don't mention that in your</p> <p>9 report, although you mention others who were</p> <p>10 on the CIR steering committee, correct?</p> <p>11 A. Yes, there's a paragraph where</p> <p>12 I talk about others, yes.</p> <p>13 Q. But you don't mention that the</p> <p>14 FDA is on the steering committee?</p> <p>15 A. I believe I -- I believe I've</p> <p>16 been asked that question before, and I said</p> <p>17 yes, but certainly in this report I don't</p> <p>18 believe I state that, that is true.</p> <p>19 Q. CIR solicits input from the</p> <p>20 public; is that correct?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: I would say they</p> <p>23 solicit input from industry, yes.</p> <p>24 QUESTIONS BY MR. LOCKE:</p> <p>25 Q. Well --</p> |
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| <p>1 conclusions to make my opinion, but it's</p> <p>2 certainly -- I am citing it here as it being</p> <p>3 a piece of evidence that is consistent with</p> <p>4 my opinions.</p> <p>5 Q. Sorry, I seem to have messed up</p> <p>6 my microphone. I'll try to hold it for a</p> <p>7 little bit then.</p> <p>8 Do you disagree with</p> <p>9 Dr. Cralley's report?</p> <p>10 A. I have not formed an opinion</p> <p>11 that I agree or disagree. He -- with his --</p> <p>12 I believe he has information that is</p> <p>13 consistent with the opinion I'm expressing in</p> <p>14 the sentence, however.</p> <p>15 Q. And do you know that</p> <p>16 Dr. Cralley repeatedly cites to the CIR as an</p> <p>17 authoritative source regarding cosmetic</p> <p>18 ingredients?</p> <p>19 A. I don't know that he uses that</p> <p>20 exact language, but he does cite to it, yes,</p> <p>21 in his report. Certainly he does.</p> <p>22 Q. More than 20 times, right?</p> <p>23 A. That, I have not counted. I</p> <p>24 can't tell you that. But he does, just like</p> <p>25 I do, as a source of information when there</p> | <p>1 A. But they -- and they do have a</p> <p>2 public comment period, which is mainly input</p> <p>3 from industry.</p> <p>4 But I agree that they do -- and</p> <p>5 if what you're referring to is a public</p> <p>6 comment period, yes, there is that for the</p> <p>7 documents.</p> <p>8 Q. You can go on the website and</p> <p>9 see what ingredients CIR is going to review,</p> <p>10 right?</p> <p>11 A. Yes, you can.</p> <p>12 Q. Have you done that?</p> <p>13 A. Yes, I've done it many times</p> <p>14 before.</p> <p>15 Q. Okay. And did you submit</p> <p>16 comments on talc in 2012?</p> <p>17 A. No, I did not.</p> <p>18 Q. Okay. You could -- the public</p> <p>19 can submit comments many times during the</p> <p>20 process of an ingredient review; is that</p> <p>21 correct?</p> <p>22 A. There are different --</p> <p>23 different stages of the draft document. Is</p> <p>24 that what you're asking me? Yes, that can be</p> <p>25 done.</p> |

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| <p>1 Q. Well, even before it's a draft, 2 CIR is soliciting information about the 3 ingredient to include in the initial 4 materials provided to the expert panel; isn't 5 that correct? 6 A. Technically I believe that is 7 true, but I would disagree that that is 8 something that happens routinely. But I 9 would agree that -- I would say technically 10 you may be -- that is something that could 11 occur, yes, but that is not the situation, 12 for example, in the case of talc. 13 Q. Why not? 14 A. Based upon what I have seen 15 described as how the review was done, and 16 that has to do with the testimony of 17 different -- or different documents that I've 18 reviewed and the testimony of individuals 19 related to this document. 20 Q. Well, Dr. Cramer could have 21 submitted comments to the CIR regarding talc, 22 couldn't he? 23 MR. MEADOWS: Objection. 24 MS. PARFITT: Objection. 25 THE WITNESS: You'd have to ask</p> | <p>1 submitted. 2 Q. And CIR meetings are open to 3 the public, right? 4 A. That is true, they are open to 5 the public, but in my experience it -- they 6 are not meetings that are heavily attended by 7 the public but indeed are -- tend to be 8 meetings attended by industry stakeholders 9 within the ingredients that are being 10 reviewed. 11 Q. You know Mr. Steinberg here. 12 He was a plaintiff's expert for a while? 13 A. I don't know him personally, 14 but I know his name and I know he was a 15 plaintiff's expert, yes. 16 Q. You know he attended the talc 17 meeting, right? 18 A. Yes, I believe he was working 19 with indus -- he works with industry, so I 20 believe indeed he did attend that meeting. 21 Q. You're not claiming he was 22 working with any industry member regarding 23 talc, are you? 24 A. That's not what I stated. I 25 know he's a consultant to the cosmetic</p> |
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| <p>1 Dr. Cramer if he was aware that they 2 were reviewing it. I can't answer 3 that for Dr. Cramer. 4 But if he was aware of it, 5 certainly -- if you're aware of the 6 process going on and the timing of it, 7 certainly you can submit comments. 8 I'm not disagreeing with you on that. 9 That is true. 10 QUESTIONS BY MR. LOCKE: 11 Q. CIR publishes in advance what 12 it's going to review; isn't that correct? 13 A. What is coming up for review? 14 Q. Yes. 15 A. Yes, things that are proposed 16 for the next meeting, yes, that's true. 17 Q. And you could submit comments 18 to the first draft of the CIR report; isn't 19 that correct? 20 A. I would agree that that is 21 possible to happen, yes. 22 Q. And you can submit comments 23 before the final report is drafted, correct? 24 A. Yes, as long as it's still in 25 draft form, yes, those comments can be</p> | <p>1 industry, so it doesn't surprise me. And I 2 believe he lives in the area, so it doesn't 3 surprise me that he attended. 4 I haven't spoken to him about 5 any of that, though, so I have no specific 6 details of that. 7 Q. Transcripts of the meeting are 8 available to the public, right? 9 A. You can download the 10 transcripts, yes. 11 Q. They're on the website? 12 A. That's what I said. You can 13 download. I'm sorry. 14 Q. Okay. 15 A. Yes, you can download them from 16 the website. 17 Q. Did you submit comments to the 18 CIR regarding talc? 19 A. No, I did not. 20 Q. Why not? 21 A. I wasn't aware of the process 22 that was going on in the draft form at the 23 time. 24 Q. Why is that? 25 A. I was not following the CIR for</p> |

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| <p>1 talc at that particular time. I have a lot 2 of other clients and a lot of other issues 3 that go on on a routine basis, and I -- I 4 literally would not have time to follow every 5 assessment they do, considering that they do 6 thousands of chemicals. 7 Q. Did you know of the CIR prior 8 to your retention by plaintiff's counsel? 9 A. Yes. In fact, I -- one of the 10 journals that I receive, International 11 Journal of Toxicology, maybe, publishes many 12 of their safety assessments. So I certainly 13 am, yes. 14 I was aware -- when I was at 15 Eviron, I was aware of the existence of CIR. 16 Q. Have you ever provided prior to 17 this litigation -- and by "this litigation" I 18 mean any aspect of the talc litigation -- an 19 expert opinion on cosmetics' ingredients? 20 A. You're asking me in any other 21 litigation on a cosmetic ingredient? 22 I'm thinking back to the cases 23 I've worked on. Not as a -- not as a 24 testifying expert. 25 At Eviron, though, we worked on</p> | <p>1 same level of review of any of these 2 ingredients as can be provided -- as was 3 provided by the IARC. 4 And so, again, that's one of 5 the comparisons I'm doing. I'm talking about 6 the difference in the time, the effort, the 7 difference in the independence of the 8 reviews. And so that -- when I'm talking 9 about, those numbers, that's what I'm 10 focusing on. I'm focusing on the fact that 11 you have so many reviews in a very short 12 period of time, with a one-expert panel, it's 13 impossible for that level of analysis and 14 review to be anywhere near what IARC panels 15 do, and also nowhere near the level of review 16 that I have done based on the number of 17 documents that I have analyzed and looked at. 18 So it's a different type of review. 19 Q. Let me ask you a few questions 20 because you have criticized the panel. 21 You would agree with that, 22 correct? 23 A. Yes. Oh, absolutely. This 24 particular analysis I have. I have made some 25 general criticisms of the overall process,</p> |
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| <p>1 litigation involving cosmetic ingredients, 2 thought I was not the testifying expert. 3 Q. In your report you talk about 4 the percentage of -- or the number of 5 ingredients that the CIR listed as unsafe. 6 Do you recall that? 7 A. Yes. I mean, if you want me to 8 verify the number, I need to go there. But, 9 yes. 10 Q. You don't mention that CIR has 11 put limitations on approximately 50 percent 12 of the ingredients that it has reviewed, do 13 you? 14 A. I don't mention that, but they 15 do. They have -- they have -- when they have 16 a statement about safety, they will -- they 17 will often talk about the limitations from 18 the safe use based on either concentration or 19 even maybe route of exposure, that is true. 20 Q. Why don't you do that? Why 21 didn't you include that in your report? 22 A. No particular reason. I mean, 23 the point I'm trying to make is really the 24 workload that's going on here and the 25 impossibility of the task of providing the</p> | <p>1 and then I made some specific criticisms of 2 this particular review. 3 Q. And one of your criticisms is 4 that the CIR -- I think you said two CIR 5 expert panelists had conflicts of interest; 6 is that correct? 7 A. Yes, that -- they did, that 8 were not -- that were not -- I believe not 9 understood even by Dr. Andersen at that time. 10 I think these are things brought up to him 11 that he was not aware of. 12 Q. All right. Now, you read his 13 testimony in one of the trials in California, 14 right? 15 A. Yes, that's the -- in fact, 16 that's the source of the information where 17 I'm citing to those names of those 18 individuals. I think I refer to that, his 19 trial testimony. 20 Q. And didn't he, though, say, 21 well, he didn't view it as a conflict of 22 interest because the money wasn't going to 23 them personally, it was going to their 24 organizations? 25 A. He did make that statement,</p> |

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| <p>1 yes.</p> <p>2 Q. And you disagree with that</p> <p>3 statement?</p> <p>4 A. I don't -- I mean, his</p> <p>5 testimony is what it is.</p> <p>6 Are you asking me do I disagree</p> <p>7 that that's a conflict of interest?</p> <p>8 I disagree that you shouldn't</p> <p>9 disclose that as a potential conflict in the</p> <p>10 documents that are produced, just like I do</p> <p>11 when I write an article and I disclose that</p> <p>12 I've had funding. I don't say what the</p> <p>13 funding specifically paid for, but I've had</p> <p>14 funding or support from this industry</p> <p>15 individual or that industry individual.</p> <p>16 It's -- it's something that just is about</p> <p>17 transparency.</p> <p>18 Q. So when you write articles, you</p> <p>19 say that you've been paid a lot of money by</p> <p>20 plaintiffs' lawyers?</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: Well, I haven't</p> <p>24 written an article that overlaps with</p> <p>25 an issue that I've addressed in</p> | <p>1 from an industry or a company that has</p> <p>2 to do with the issue you're looking</p> <p>3 at, yes, a conflict -- a conflict of</p> <p>4 interest absolutely needs to be</p> <p>5 described.</p> <p>6 QUESTIONS BY MR. LOCKE:</p> <p>7 Q. And that would -- well, let me</p> <p>8 just ask you: You're not an ethicist, are</p> <p>9 you?</p> <p>10 A. No, I'm not trained as an</p> <p>11 ethicist.</p> <p>12 Q. And you're not a lawyer, are</p> <p>13 you?</p> <p>14 A. Well, no, but I have passed the</p> <p>15 patent bar, but I'm not trained as a lawyer.</p> <p>16 Q. That doesn't make you an</p> <p>17 ethicist, right?</p> <p>18 A. No, it does not.</p> <p>19 Q. Okay. Let's talk about one of</p> <p>20 the people you criticized, Dr. Wilma</p> <p>21 Bergfeld.</p> <p>22 Did you know she was the first</p> <p>23 woman who was the president -- to be the</p> <p>24 president of the American Academy of</p> <p>25 Dermatology?</p> |
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| <p>1 plaintiffs' litigation, but I</p> <p>2 certainly have given my conflict of</p> <p>3 interest statements that relate to the</p> <p>4 issue in the article.</p> <p>5 I do that -- I've done that</p> <p>6 with -- on my work -- several of my --</p> <p>7 several of my assessments talking</p> <p>8 about risks of pesticides. I've done</p> <p>9 it with the work that I've done that</p> <p>10 that's been sort of, I guess,</p> <p>11 policy-type work on behalf of the</p> <p>12 American Chemistry Council.</p> <p>13 So absolutely I do.</p> <p>14 QUESTIONS BY MR. LOCKE:</p> <p>15 Q. Okay. You don't think it's</p> <p>16 relevant that you receive 50 percent of your</p> <p>17 money solely from plaintiffs' products</p> <p>18 liability lawyers?</p> <p>19 MR. MEADOWS: Objection.</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 THE WITNESS: If it has nothing</p> <p>22 to do with the issue that I'm</p> <p>23 addressing in the paper, no, I do not</p> <p>24 think that.</p> <p>25 But when you're accepting money</p> | <p>1 A. No, I don't know her</p> <p>2 personally, so, no, I did not know that.</p> <p>3 Q. Did you investigate her at all</p> <p>4 when you criticized her?</p> <p>5 A. I wasn't criticizing her, I was</p> <p>6 criticizing the CIR process for failing to</p> <p>7 disclose the conflicts of interest of</p> <p>8 individuals that were involved in their</p> <p>9 assessment.</p> <p>10 I certainly am not giving</p> <p>11 personal criticism to either of those</p> <p>12 individuals.</p> <p>13 Q. You would agree that the</p> <p>14 American Academy of Dermatology is a</p> <p>15 reputable organization?</p> <p>16 A. I haven't formed an opinion one</p> <p>17 way or the other; however, I'm aware of them,</p> <p>18 and certainly I know individuals that are</p> <p>19 members of it, yes.</p> <p>20 Q. Are those individuals reputable</p> <p>21 people?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: They are people</p> <p>24 that practice medicine that certainly</p> <p>25 I would go see. I mean, you're asking</p> |

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| <p>1 me if I formed a very specific opinion</p> <p>2 about them as individuals, and I</p> <p>3 haven't done that.</p> <p>4 QUESTIONS BY MR. LOCKE:</p> <p>5 Q. Do you have any reason to</p> <p>6 believe that the American Academy of</p> <p>7 Dermatology is disreputable?</p> <p>8 A. No. Again, I haven't formed an</p> <p>9 opinion one way or the other. I'm aware of</p> <p>10 the organization, and it certainly is one</p> <p>11 that is -- has within its members a number of</p> <p>12 people that I know that practice in</p> <p>13 dermatology.</p> <p>14 Q. Did you know that Dr. Bergfeld</p> <p>15 was the first woman to be president of the</p> <p>16 Cleveland Academy of Medicine?</p> <p>17 A. To the what? What was the</p> <p>18 first word?</p> <p>19 Q. Cleveland Academy of Medicine?</p> <p>20 A. No. Again, I'm not aware of</p> <p>21 her CV specifically, other than what may have</p> <p>22 been discussed -- it's possible her -- I know</p> <p>23 her affiliation will be listed in some of the</p> <p>24 documents as to where she is today, but I do</p> <p>25 not know her CV and her history.</p> | <p>1 and also gynecological -- gynecological</p> <p>2 sciences on the issue of migration.</p> <p>3 Q. You're not a epidemiologist,</p> <p>4 are you?</p> <p>5 A. Not by training. It's a tool I</p> <p>6 use all the time, but I'm not an</p> <p>7 epidemiologist by training.</p> <p>8 Q. And panel members on the CIR,</p> <p>9 they might have used the same tool that</p> <p>10 you're using to form your opinion about talc,</p> <p>11 correct?</p> <p>12 MR. MEADOWS: Objection.</p> <p>13 THE WITNESS: Based on what</p> <p>14 I've reviewed from the minutes and the</p> <p>15 write-up, I would disagree that that</p> <p>16 is -- they have done -- they've used</p> <p>17 the tools in the same way I have. I</p> <p>18 disagree with that.</p> <p>19 QUESTIONS BY MR. LOCKE:</p> <p>20 Q. No, but I'm saying their</p> <p>21 epidemiology could be the same background</p> <p>22 that you have. You haven't reviewed who they</p> <p>23 are, so you really don't really know.</p> <p>24 MR. MEADOWS: Objection.</p> <p>25 THE WITNESS: Well, I do</p> |
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| <p>1 Q. Are you aware that she was the</p> <p>2 first president -- or she was a president of</p> <p>3 the American Society of Dermatopathology?</p> <p>4 A. No. Same thing. If I'm not</p> <p>5 aware of her CV, I wouldn't know that.</p> <p>6 Q. How about that she was the</p> <p>7 former chair to the FDA's drug -- FDA's</p> <p>8 Dermatology and Ophthalmology Advisory</p> <p>9 Committee?</p> <p>10 A. Same answer. I don't know her</p> <p>11 CV, so I have no knowledge.</p> <p>12 Q. Is it your opinion that</p> <p>13 Dr. Bergfeld was not qualified to chair the</p> <p>14 CIR panel that considered talc?</p> <p>15 A. I don't think I formed that</p> <p>16 specific opinion. Instead, what I have --</p> <p>17 the opinions I formed relate to the overall</p> <p>18 makeup of the panel that failed to include</p> <p>19 individuals with expertise that were -- that</p> <p>20 are really key to assessing the safety of</p> <p>21 talc. And that had to do with the issues of,</p> <p>22 as I discuss it, epidemiology -- oh, I'm</p> <p>23 sorry, I think I need to put this back --</p> <p>24 period -- sorry. In the area of epidemiology</p> <p>25 is one that I talked about it specifically,</p> | <p>1 know -- I do know Dr. Klaassen, who I</p> <p>2 believe was on the panel as a</p> <p>3 toxicologist. He is not somebody</p> <p>4 that -- he is not somebody that I</p> <p>5 understand does a significant amount</p> <p>6 of evaluation in risk assessment for</p> <p>7 epidemiological studies. He has done</p> <p>8 some of that, yes, I agree, but it's</p> <p>9 different training than mine.</p> <p>10 QUESTIONS BY MR. LOCKE:</p> <p>11 Q. You're better qualified than he</p> <p>12 is?</p> <p>13 A. No, that's not what I'm saying.</p> <p>14 I'm saying it's different background.</p> <p>15 The question that I heard you</p> <p>16 ask me, I believe, was directed towards the</p> <p>17 differences in my background versus somebody</p> <p>18 else's.</p> <p>19 And I'm saying that I'm not</p> <p>20 aware that he has the same background I do,</p> <p>21 but there is not -- there was not somebody on</p> <p>22 the panel that had specific expertise and</p> <p>23 analysis of epidemiological studies as an</p> <p>24 epidemiologist. And I think that's important</p> <p>25 in this case where you're analyzing in a</p> |

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| <p>1 causation analysis a wide variety of studies. 2 So I do think it's important. 3 Q. You're not a gynecological 4 oncologist, are you? 5 A. No, I'm not. But again, that 6 would have been an important expertise to 7 have on the panel when -- 8 Q. And yet you formed your opinion 9 with -- 10 MR. MEADOWS: Hold on. 11 MR. LOCKE: No. No. Go ahead. 12 You can ask follow-up questions 13 if you want. 14 MR. MEADOWS: You're 15 interrupting her. 16 MR. LOCKE: Well, I've got a 17 limited amount of time, and I've got 18 to keep moving. 19 MR. MEADOWS: Well -- 20 MR. LOCKE: They're very long 21 answers to questions that I'm not 22 asking. So I -- you follow up if you 23 would like with your questions, but I 24 got to keep moving. 25 MR. MEADOWS: Well, I'm sorry,</p> | <p>1 I'm sorry. 2 Q. The FDA frequently seeks 3 information, scientific information, from 4 cosmetic manufacturers; is that correct? 5 A. I don't understand what you 6 mean by "frequently seeks." They rely on 7 cosmetic manufacturers to do their own safety 8 assessments. 9 Is that what you're referring 10 to? 11 Q. Well, they ask PCPC to comment 12 on scientific issues, correct? 13 A. Yes, I would agree that that 14 interaction has happened, but that's not 15 where the responsibility lies. But I agree, 16 they have. 17 Q. I'm not asking about 18 responsibility. I'm asking: Has the FDA 19 asked cosmetic manufacturers for scientific 20 information? 21 A. Yes, they have in this case. I 22 discuss some of that, yes. 23 Q. And they do that frequently, 24 right? Not just in this case, but generally? 25 A. I can't answer that for all</p> |
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| <p>1 but you're not going to be allowed to 2 interrupt her. 3 MR. LOCKE: Okay. Then we'll 4 go longer. If she's going to answer 5 questions I'm not asking, then I need 6 to go -- I need to be able to go 7 longer. 8 MR. MEADOWS: You're not going 9 to be allowed to interrupt her. 10 That's just the bottom line. 11 QUESTIONS BY MR. LOCKE: 12 Q. You're not a gynecological 13 oncologist, right? 14 A. I'm not trained as a 15 gynecologic oncologist, that is true. 16 Q. You're not a medical doctor, 17 correct? 18 A. I am not a physician, that is 19 correct. 20 Q. Let's talk about the citizens 21 petition. 22 The FDA frequently seeks 23 scientific information from cosmetic 24 manufacturers; is that correct? 25 A. First part of the question?</p> | <p>1 situations. I have seen it happen before, 2 yes. 3 Q. The FDA asked, for example, for 4 then CTFA to cosponsor the 1994 workshop on 5 talc, correct? 6 A. Yes, they did. 7 Q. The FDA knew that the report 8 prepared by Dr. Huncharek and Dr. Muscat was 9 based on PCPC's retention of those 10 consultants, correct? 11 A. So what are you -- what time 12 period are you talking about? 13 Q. Well, now, there was only one 14 time that Drs. Huncharek and Muscat submitted 15 a report to the FDA regarding talc, correct? 16 A. So I need to look to confirm 17 that. Which time period are you talking 18 about? 19 Q. 2009. Citizens petition. 20 A. Oh, that is true. In the 21 citizens petition, that is true, yes. But 22 I -- but... 23 Q. I mean, it says in the letter, 24 "We're submitting a report written by Drs. 25 Huncharek and Muscat," correct?</p> |

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| <p>1 A. In the cover letter from the 2 CRE? 3 Q. From -- not CRE, from PCPC. 4 A. Okay. So let -- I need to -- I 5 need to refresh my memory on the way the 6 submissions were made. I apologize. 7 Do you remember which paragraph 8 that you're referring to? 9 Q. Well, it's throughout your 10 report you're talking about the citizens 11 petition. 12 A. So it's my recollection, based 13 upon the documents that I have seen, that it 14 was not a transparent process at all times 15 that Drs. Huncharek and Muscat were being 16 identified as independent consultants and 17 were not ones that were being actually paid 18 by the industry for some of the work that 19 they did. And I think that's discussed in my 20 report. 21 Q. Well, let's break that down. 22 A. If you want me to confirm the 23 issue of the 2009 -- if you will point me to 24 where you say I discuss this, I will confirm 25 that or not.</p> | <p>1 Q. And you're not aware of any 2 other document indicating that PCPC ever 3 hired Drs. Huncharek or Muscat? 4 A. So that's where I'll need to go 5 back and look at the documents, because -- 6 that I have discussed. So I need to find 7 that on my paragraph. 8 If you want to go off the 9 record for a minute so I don't waste your 10 time, I will look. 11 Q. Sure. 12 A. It's up to you. Or we can stay 13 on the record. 14 MR. LOCKE: I'm fine going off. 15 VIDEOGRAPHER: We are going off 16 the record at 4:23 p.m. 17 (Off the record at 4:23 p.m.) 18 VIDEOGRAPHER: We are back on 19 the record at 4:25 p.m. 20 QUESTIONS BY MR. LOCKE: 21 Q. The question I asked: Are you 22 aware of any other document indicating that 23 PCPC ever hired Dr. Huncharek and Muscat 24 other than for the 2009 response or 25 submission to the citizens petition?</p> |
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| <p>1 Q. Well, let me break it down. 2 Citizens petition submitted in 3 2008, right? 4 A. Well, there were two: one in 5 1994 and another -- I'm sorry, 1992, and 6 another in 2008. 7 Q. Well, there are actually 8 several more than that, but let's just focus 9 on the 2008. 10 In 2008, a citizens petition 11 was submitted? 12 A. Yes, that is true. 13 Q. And PCPC responded to that 14 citizens petition in 2009, correct? 15 A. They submitted comments. Is 16 that what you're asking me? Yes, they did. 17 Q. Yes. 18 And that was a cover letter, 19 correct? 20 A. A cover letter -- that's all it 21 was was a cover letter? 22 Q. Well, attached to the cover 23 letter was a report from Drs. Huncharek and 24 Muscat? 25 A. Yes, that is true.</p> | <p>1 A. I would have to pull this 2 document, but in paragraph 90 I make a 3 statement: A 2005 response written by 4 Dr. Muscat says -- this is not '09, this is 5 2005, and Dr. Huncharek critiqued the work of 6 Dr. Cramer, who also failed to disclose the 7 financial relation -- I'll start over. 8 Okay. So I'm sorry to repeat 9 myself, but there was a little noise. 10 You asked 2009. So the other 11 time period I have in my report in 12 paragraph 90 talks about 2005, but I'd have 13 to pull this document. 14 But I am citing to the 15 deposition of Dr. Loretz, who was a PCPC 16 employee, so I think I would need to pull 17 this in order to confirm. 18 But I see depositions of her 19 and Dr. Nicholson as talking about them 20 failing to disclose the financial 21 relationship between their work and industry. 22 Q. So if Dr. Loretz did not 23 testify that PCPC had retained Drs. Huncharek 24 and Muscat in 2005, you'd have no other 25 evidence?</p> |

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| <p>1 A. I can't answer that 2 definitively, but this is what I would point 3 you to. So I'd have to pull these documents 4 to confirm, but I have -- both paragraphs 89 5 and 90 address these general issues for you, 6 but I think that's the sentence and the 7 documents that I think would be relevant. 8 But I'd have to pull them to fully answer 9 your question. 10 Q. The reason I ask the question 11 is because you frequently say "the cosmetics 12 industry" without identifying a party or a 13 person. And -- well, I'll just leave it at 14 that. 15 A. And I guess the reason I'm 16 saying I need to -- I'm questioning that it 17 doesn't have to do with PCPC is because I am 18 citing to a deposition of their employee. So 19 I need to -- I would -- to affirm it, though, 20 I'd need to -- I don't want to say that 21 100 percent the answer to your question is 22 this is the evidence, but I believe that I 23 would need to go here to confirm one way or 24 the other. But certainly I would -- this 25 raises suspicion about that for me.</p> | <p>1 Q. What evidence do you have of 2 that? 3 A. Based upon the close 4 interaction between PCPC, Imerys and Johnson 5 & Johnson throughout these time periods when 6 different actions were being taken to comment 7 or to submit information on behalf of 8 industry. 9 Q. Do you have a single document 10 you can point to or is that an assumption? 11 A. That is something I seem to 12 remember based on my review of these 13 documents, but if you need a document, I 14 would have to -- have to go and look for it. 15 Q. Sitting here today, you can't 16 recall? 17 A. I can't give you a specific 18 document as I sit here today, no. 19 MR. LOCKE: I have no further 20 questions. 21 MR. MEADOWS: Yeah, short 22 break. Maybe we're done, maybe we're 23 not. 24 VIDEOGRAPHER: We are going off 25 the record at 4:30 p.m.</p> |
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| <p>1 Q. You have no evidence that PCPC 2 ever retained the Center for Regulatory 3 Effectiveness; is that correct? 4 A. I believe my evidence is hiring 5 through Imerys, but let me look to make sure 6 that is true. 7 Q. Why don't you look at page -- 8 or I'm sorry, paragraph 95, page 63. 9 A. That's where I am. That's 10 where I am, so let me read what I have here 11 because it's been a while since I've read 12 this paragraph. 13 So the question is, do I have 14 in evidence this paragraph that PCPC directly 15 hired the CRE? 16 No, that is not provided by 17 this paragraph. 18 Q. Okay. 19 A. However, in this paragraph, 20 based on these documents that I'm seeing and 21 I'm -- my memory of what is discussed, 22 certainly I believe PCPC would have been 23 aware of the interaction of CRE at these time 24 points when I'm talking about this event -- 25 these events.</p> | <p>1 (Off the record at 4:30 p.m.) 2 VIDEOGRAPHER: We are back on 3 the record at 4:45 p.m. 4 CROSS-EXAMINATION 5 QUESTIONS BY MS. PARFITT: 6 Q. All right. Dr. Plunkett, good 7 afternoon. I know it's been a long day. 8 Dr. Plunkett, you were asked 9 throughout the course of the day about 10 different constituents which are part of the 11 talcum powder products. 12 Do you recall those questions? 13 A. Yes. 14 Q. All right. If -- without going 15 through each and every one of different 16 constituents that we've talked about that are 17 contained or could be contained in the talcum 18 powder products, if they are present, do 19 those various constituents present and 20 provide biologically plausible evidence that 21 talcum powder products can increase the risk 22 of ovarian cancer? 23 MS. BOCKUS: Object to the 24 form. 25 THE WITNESS: Yes, which is --</p> |

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| <p>1 I think I have a couple of paragraphs 2 where I talk about that issue. It has 3 to do -- there's other information as 4 well, but that is a key piece of that 5 information. And I focused on mode of 6 action and additivity. That's on 7 mechanism, biologic plausibility. 8 So the fact that you have a 9 variety of constituents that have a 10 known cancer hazard that share a mode 11 of action, that increases your 12 confidence in the biologic 13 plausibility of that relationship 14 between ovarian cancer and exposure to 15 talc body powders, yes. 16 MS. PARFITT: Thank you. I 17 have no further questions. Thank you 18 very much, Dr. Plunkett. And a happy 19 holiday to you. 20 THE WITNESS: Thank you. 21 MS. BRANSCOME: I have no 22 questions. 23 MS. BOCKUS: No questions. 24 VIDEOGRAPHER: The time now is 25 4:47 p.m. This concludes the</p> | <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomate Reporter, Certified Realtime 5 Reporter and Certified Shorthand Reporter, do 6 hereby certify that prior to the commencement 7 of the examination, Laura Plunkett, Ph.D., 8 DABT was duly sworn by me to testify to the 9 truth, the whole truth and nothing but the 10 truth. 11 I DO FURTHER CERTIFY that the 12 foregoing is a verbatim transcript of the 13 testimony as taken stenographically by and 14 before me at the time, place and on the date 15 hereinbefore set forth, to the best of my 16 ability. 17 I DO FURTHER CERTIFY that I am 18 neither a relative nor employee nor attorney 19 nor counsel of any of the parties to this 20 action, and that I am neither a relative nor 21 employee of such attorney or counsel, and 22 that I am not financially interested in the 23 action. 24 25 CARRIE A. CAMPBELL, NCRA Registered Diplomate Reporter Certified Realtime Reporter California Certified Shorthand Reporter #13921 Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter #084-004229 Texas Certified Shorthand Reporter #9328 Kansas Certified Court Reporter #1715 Notary Public Dated: 12/20/18</p> |
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| <p>1 deposition, and we are going off the 2 record. 3 (Deposition concluded at 4:47 p.m.) 4 ----- 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> | <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p> |

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| 2 | | 2 | LAWYER'S NOTES |
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| 4 | I, _____, do | 4 | PAGE LINE |
| 5 | hereby certify that I have read the foregoing | 5 | _____ |
| 6 | pages and that the same is a correct | 6 | _____ |
| 7 | transcription of the answers given by me to | 7 | _____ |
| 8 | the questions therein propounded, except for | 8 | _____ |
| 9 | the corrections or changes in form or | 9 | _____ |
| 10 | substance, if any, noted in the attached | 10 | _____ |
| 11 | Errata Sheet. | 11 | _____ |
| 12 | | 12 | _____ |
| 13 | _____ Laura Plunkett, Ph.D., DABT DATE | 13 | _____ |
| 14 | | 14 | _____ |
| 15 | Subscribed and sworn to before me this | 15 | _____ |
| 16 | _____ day of _____, 20 ____. | 16 | _____ |
| 17 | My commission expires: _____ | 17 | _____ |
| 18 | | 18 | _____ |
| 19 | Notary Public | 19 | _____ |
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